

**FINAL** REGISTRATION REPORT

**Part B**

**Section 9**

**Ecotoxicology**

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.

Submission date: February 2018

**MS Finalisation date: 18/10/2022**

## Version history

When	What
February 2018	Submission to the Polish Ministry of Agriculture and Rural Development
October 2018	Submission to the evaluation unit
December 2018	Applicant update
2020	GAP table updated by the Applicant
August 2020	Applicant update: summaries of fish, daphnia, algae, lemna, bee acute, chronic and larval, non target arthropods, earthworm, springtail, soil mites and soil microorganisms studies; risk assessments ammended
October 2021	NTP studies included. RA updated
October 2021	zRMS finalised evaluation
October 2022	Final version prepared by zRMS after Commenting period

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## 9 Ecotoxicology (KCP 10)

### **Review Comments:**

This application was submitted by Sharda Poland Sp. z o. o. for approval of SHA 110 D (CANDELA) a soluble concentrate containing 540 g/l of glyphosate for use as a herbicide on winter cereals, spring barley, oilseed rape, sunflower, maize, pome fruit, grapevine and stone fruit.

This Part B document only reviews data (Annex III) and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.

In addition, it should be noted that, during the evaluation of the dossier, the Applicant modified the proposed use pattern of the Candela. For this reason, a risk assessment was performed for the higher dose rate of the product proposed in the original GAP. Only for mammals, for which a high risk has been identified, zRMS performed recalculation of TERs for the lower dose rate, currently proposed for use in orchards, vineyards and before seedling (grasslands scenario).

## 9.1 Critical GAP and overall conclusions

**Table 9.1-1: Table of critical GAPs (old version)**

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 <sub>7</sub> F <sub>8</sub> G <sub>7</sub> G <sub>8</sub> G <sub>9</sub> or I**	Pests-or-Group-of-pests controlled (additionally: developmental-stages of-the-pest-or-pest group)	Application				Application-rate			PHI (days)	Remarks: e.g.-g-saf- ener/ synergist per-ha							
					Method-/ Kind	Timing-/ Growth stage-of-crop &-season	Max. number a)-per-use b)-per-crop/ season	Min.-interval between applications (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									
Zonal-uses (field-or-outdoor-uses, certain-types-of-protected-crops)																				
1	CEU	Winter-cereals (wheat,barley, rye,oats, triticale)	F	Annual-and-perennial grass-and-broadleaved weeds	Foliar-Spray	Application before seedling	a)-1 b)-1	-	a)-3.5 b)-3.5	a)-1.89 b)-1.89	200-400	-								
2	CEU	Winter-wheat	F	Desiccation-before harvest	Foliar-Spray	BBCH-89	a)-1 b)-1	-	a)-2 b)-2	a)-1.08 b)-1.08	200-400	7								
3	CEU	Oilseed-rape	F	Annual-and-perennial grass-and-broadleaved weeds	Foliar-Spray	Application before seedling	a)-1 b)-1	-	a)-3.5 b)-3.5	a)-1.89 b)-1.89	200-400	-								
4	CEU	Spring-barley	F	Annual-and-perennial grass-and-broadleaved weeds	Foliar-Spray	Application before seedling	a)-1 b)-1	-	a)-3.5 b)-3.5	a)-1.89 b)-1.89	200-400	-								
5	CEU	Sunflower	F	Annual-and-perennial grass-and-broadleaved weeds	Foliar-Spray	Application before seedling	a)-1 b)-1	-	a)-3.5 b)-3.5	a)-1.89 b)-1.89	200-400	-								
6	CEU	Maize	F	Annual-and-perennial grass-and-broadleaved weeds	Foliar-Spray	Application before seedling	a)-1 b)-1	-	a)-3.5 b)-3.5	a)-1.89 b)-1.89	200-400	-								
7	CEU	Pome-fruit (Apple,pear)	F	Annual-and-perennial grass-and-broadleaved weeds	Foliar-Spray	Spring application BBCH-31-69	a)-1 b)-1	-	a)-3.5 b)-3.5	a)-1.89 b)-1.89	800-1000	-								

1	2	3	4	5	6	7	8	9	10	11	12	13	14							
8	CEU	Grapevine	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring application BBCH 13-69	a) 1 b) 1	-	a) 3-5 b) 3-5	a) 1-89 b) 1-89	600-1000	-								
9	CEU	Stone-fruit (Peach, apricot, plum, cherry)	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring application BBCH 31-59	a) 1 b) 1	-	a) 3-5 b) 3-5	a) 1-89 b) 1-89	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

**Table 9.1-2: Table of critical GAPs (new version)**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I**	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf-ener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (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			Birds	Mammals	Aquatic organisms	Bees	Non-target	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400	-								
2	CEU	Winter wheat	F	Desiccation before harvest	Foliar Spray	BBCH 89	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400	7								
3	CEU	Oilseed rape	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400	-								
4	CEU	Spring barley	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	15	16	17	18	19	20	21
5	CEU	<b>Sunflower</b>	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400	-								
6	CEU	<b>Maize</b>	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400	-								
7	CEU	<b>Pome fruit (Apple, pear)</b>	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring application BBCH 31-69	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	800-1000	-								
8	CEU	<b>Grapevine</b>	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring application BBCH 13-69	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	600-1000	-								
9	CEU	<b>Stone fruit (Peach, apricot, plum, cherry)</b>	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring application BBCH 31-59	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	800-1000	-								

\* 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

#### Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

#### Remarks table:

- (1) Numeration necessary to allow references
- (2) Use official codes/nomenclatures of EU
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
- (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (8) The maximum number of application possible under practical conditions of use must be provided
- (9) Minimum interval (in days) between applications of the same product.
- (10) For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> 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

## 9.1.1 Overall conclusions

### 9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

#### ❖ Birds

All the  $TER_a$  and  $TER_{lt}$  values for the active substance Glyphosate are greater than the Annex VI trigger of 10 and 5, respectively, indicating that CANDELA presents no unacceptable acute and long-term risk to birds according to the intended uses.

No risk from drinking water neither due to secondary poisoning was expected.

#### ❖ Mammals

##### Bare soil

According to the screening assessments for bare soil, all the  $TER_a$  and  $TER_{lt}$  values for the active substance Glyphosate are greater than the Annex VI trigger of 10 and 5, respectively, indicating that CANDELA presents no unacceptable acute and long-term risk to mammals according to the intended uses on winter cereals, oilseed rape, spring barley, sunflower and maize.

##### Grasslands

Based on the risk assessment for mammals performed above, the safe use was confirmed for all proposed uses of CANDELA indicated in the GAP table of this report.

The acceptability of the revised endpoint used in the higher-tier long-term assessment for uses before seedling should be reviewed at national level.

##### Winter wheat (desiccation)

$TER_a$  values are greater than the trigger of 10 showing no unacceptable acute risk to mammals according to the intended uses winter wheat (desiccation). However,  $TER_{lt}$  values are greater than the trigger of 5 except for the species “vole”. A further refinement of the long-term risk was needed. A refinement of the risk was done by refining of application rate,  $DT_{50}$ , ftwa and RUD, and the TER values is above the trigger showing no risk for mammals for Glyphosate in winter wheat.

##### Orchards and grapevine

$TER_a$  and  $TER_{lt}$  values are greater than the trigger of 10 and 5 respectively, except for the species “vole” in acute and long-term risk assessment and “lagomoroph” in long-term risk assessment. A further refinement of the acute and long-term risk was needed. A refinement of the risk was done by refining of application rate,  $DT_{50}$ , ftwa and RUD, and the TER values is above the trigger showing no risk for mammals for Glyphosate in orchards and grapevine.

No risk from drinking water neither due to secondary poisoning was expected.

### 9.1.1.2 Effects on aquatic organisms (KCP 10.2)

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 ~~s-1-2-scenarios~~ 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.

#### **9.1.1.3 Effects on bees (KCP 10.3.1)**

First-tier assessments indicate that no unacceptable risk for bees exposed to the product CANDELA is expected according to the proposed intended uses.

#### **9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)**

The  $PER_{in-field}$  and corrected  $PER_{off-field}$  fall below the rate with <50% effects, indicating that CANDELA does not pose an unacceptable risk to non-target arthropods in in-field and off-field areas.

#### **9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)**

All the  $TER_a$  and  $TER_{lt}$  values for glyphosate and its metabolite AMPA are higher than the ~~Annex VI~~ trigger value of ~~10 and~~ 5, respectively, indicating a low ~~acute and~~ long-term risks to earthworms and other non-target soil organism. Therefore, CANDELA poses low ~~acute and~~ long-term risks to earthworms and other non-target soil organisms when applied according to the proposed use rates.

Risk assessments conducted with relevant  $PEC_{soil}$  for the active substance Glyphosate and its metabolite AMPA indicate a low risk to soil microorganisms. Therefore, the application of CANDELA indicate a low risk to soil microorganisms when applied according to the proposed use rates.

#### **9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)**

The refined TER value is above the relevant trigger of 5 when using a no-spray buffer zone of 10 m, indicating that of CANDELA poses an acceptable risk considering this risk mitigation measure. It should however be noted that the no-spray buffer zone could be reduced to 5 m when combined with 50% drift-reducing nozzles or any no-spray buffer zone when 90% drift-reducing nozzles are used.

##### **Implication for labelling:**

**SPe 3:** To protect non-target plants respect an unsprayed buffer zone of 10 m to non-agricultural land OR 5m to non-agricultural land with 50% drift reducing nozzles OR 90% drift reducing.

#### **9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)**

No additional data are available.

## 9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

**Table 9.1-2: Critical-use pattern of CANDELA grouped according to application rate, number of application, timing and indicator species**

Grouping according to application rate, number of application, timing and indicator species			
Group	Intended-uses	relevant-use-parameters for grouping	relevant parameter or value for sorting
Bare soil*	winter cereals, oilseed rape, spring barley, sunflower and maize	Same application rate (1.89 kg as/ha), same application period (before seedling), number of application (1) and same indicator species	Same indicator species for the assessment for birds and mammals
Orchards	Pome fruits, stone fruits	Same application rate (1.89 kg as/ha), same application period (BBCH 31-69), number of application (1) and same indicator species	Same indicator species for the assessment for birds and mammals
Grapvine	Grapvine	Application rate (1.89 kg as/ha), application period (BBCH 13-69), number of application (1) and specific indicator species	Specific indicator species for the assessment for birds and mammals
Cereals	Winter wheat	Application rate (1.08 kg as/ha), application period (BBCH 89), number of application (1) and specific indicator species	Specific indicator species and application period (BBCH 89) for the assessment for birds and mammals
All crops	winter cereals, oilseed rape, spring barley, sunflower, maize, pome fruits, stone fruits, grapevine and winter wheat (desiccation)	Same application rate (1.89 kg as/ha) or lower for winter wheat (1.08 kg as/ha) and same number of application (1) and drift value (2.77%**)	Highest application rate for assessment of drinking water for birds and mammals, for assessment of bees, earthworms and soil microorganisms Highest application rate and drift value for assessment for arthropods other than bees and non target plant

\*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 to cover all these uses.

\*\* A drift value of 2.77% is considered as an appropriate surrogate for ground directed application on orchards and grapevine since the product is an herbicide intended to be applied on weeds.

### Review comments:

The grouping of the intended uses of Candela provided by the Applicant in table above was too very general, therefore for clarity of the assessment zRMS updated critical GAP.

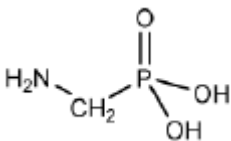
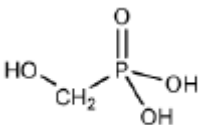
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value
<b>Terrestrial vertebrates</b> (Birds and Mammals; <b>9.2</b> and <b>9.3</b> )	According to GAP (old and new version, where necessary)	Scenarios according to EFSA Birds and Mammals Guidance (2009): For Application before seedling two scenarios were considered: - Bare soil: this scenario would be appropriate if the herbicide is to be used on bare soil with only a few weeds present; - Grassland: this scenario will cover the risk to birds and mammals for herbicide use on fields with dense weed coverage or with existing grassland before sowing or planting the following crop.	Crop, application rate, number of applications, timing criterion
<b>Aquatic organisms</b> ( <b>9.5</b> )	According to old GAP	Crops according to FOCUS surface water guidance (2015) <sup>1</sup>	FOCUS modelling, for details see Part B 8
<b>Bees</b> ( <b>9.6</b> )	Generic risk envelope covering all product uses	Risk assessments are based on the maximum single application rate	Maximum single application rate
<b>Terrestrial non-target arthropods other than bees</b> ( <b>9.7</b> )	According to old GAP In-field	In-field and off-field risk assessments are based on the maximum application rate for each type of crops	Application rate and number of uses
	According to old GAP Off-field		Crop type (height), application rate and number of uses
<b>Soil meso- and macrofauna / soil microorganisms</b> ( <b>9.8</b> and <b>9.9</b> )	Generic risk envelope covering all product uses	Risk assessments are based on the application rate of 1 x 1.89 kg s.a./ha	Worst case PECsoil value taken from Section 8 (Environmental Fate)
<b>Non-target terrestrial plants</b> ( <b>9.10</b> )	According to new GAP	Risk assessments are based on the maximum single application rate	Maximum single application rate and worst case drift rate

### 9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of CANDELA is indicated in the table.

<sup>1</sup> FOCUS (2015): Generic guidance for FOCUS surface water Scenarios. Version 1.4.

**Table 9.1-3 Metabolites of Glyphosate**

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
AMPA		111 g/mol	Soil: 53.8% Water 15.7% Sediment: 18.7%	Yes, for aquatic organisms, earthworms and soil microorganisms
HMPA		112 g/mol	Water: 10%	Yes, for aquatic organisms only

According to the RAR, December 2013, the primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). Most of the parent glyphosate is eliminated unchanged and only a small amount (less than 1% of the applied dose) is transformed to AMPA. The metabolite AMPA has been tested in several toxicity studies which demonstrated that it is of lower toxicity than glyphosate acid. Avian toxicity tests with metabolites of glyphosate showed equally low acute toxicity as glyphosate. Therefore, it can be concluded that the risk to birds and mammals will be acceptably low and no further quantitative risk assessment is conducted.

## 9.2 Effects on birds (KCP 10.1.1)

### 9.2.1 Toxicity data

Avian toxicity studies have been carried out with Glyphosate and its relevant metabolite. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of CANDELA were not evaluated as part of the EU assessment of Glyphosate.

However, the provision of further data on the CANDELA is not considered essential, because active substance data on toxicity to birds can be used and additional formulation data are not considered essential.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds**

Species	Substance	Exposure System	Results	Reference
Bobwhite quail	Glyphosate acid	Acute	LD <sub>50</sub> = 4334 mg/kg bw (extrapolated with factor 2.167)	EFSA Journal 2015;13(11):4302
Bobwhite quail	AMPA	Acute	LD <sub>50</sub> > 2250 mg/kg bw	EFSA Journal 2015;13(11):4302
Bobwhite quail	Glyphosate acid	Short-term	LDD <sub>50</sub> > 5200 mg/kg bw/d	EFSA Journal 2015;13(11):4302
Bobwhite quail	AMPA	Short-term	LDD <sub>50</sub> > 5620 mg/kg bw/d	EFSA Journal 2015;13(11):4302
Bobwhite quail	Glyphosate acid	Long term	NOEL = 96.3 mg/kg bw/d	EFSA Journal 2015;13(11):4302
Mallard duck	Glyphosate acid	Long term	NOEL = 125.3 mg/kg bw/d	EFSA Journal 2015;13(11):4302

#### 9.2.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

#### 9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil and grassland also covers the risk for birds from all other intended uses before seedling in groups bare soil and the assessment for the use group orchards and grapevine also covers the risk for birds from all other intended uses in groups orchards (see 9.1.2). In addition, the use grapevine

and winter wheat for desiccation have also been assessed separately.

### 9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

**Table 9.2-2: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of CANDELA in grassland bare soil (before seedling of winter cereals, oilseed rape, spring barley, sunflower and maize)**

<b>Intended use</b>		Bare soil before seedling (winter cereals, oilseed rape, spring barley, sunflower and maize)				
<b>Active substance/product</b>		Glyphosate				
<b>Application rate (g/ha)</b>		1 × 1890				
<b>Acute toxicity (mg/kg bw)</b>		4334				
<b>TER criterion</b>		10				
<b>Crop scenario</b>	<b>Indicator species for screening</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub> (mg/kg bw/d)</b>	<b>TER<sub>a</sub></b>	
Bare soil and hops	Small granivorous bird	24.7	1	46.68	92.8	
Grassland	Large herbivorous bird	30.5	1	57.65	75.2	
<b>Reprod. toxicity (mg/kg bw/d)</b>		96.3				
<b>TER criterion</b>		5				
<b>Crop scenario</b>	<b>Indicator species for screening</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>lt</sub></b>	
Bare soil and hops	Small granivorous bird	11.4	1 x 0.53	11.42	8.4	
Grassland	Large herbivorous bird	16.2	1 x 0.53	16.23	5.9	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.2-3: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of CANDELA in Orchards (pome/stone fruits)**

<b>Intended use</b>		Orchards (pome/stone fruits)				
<b>Active substance/product</b>		Glyphosate				
<b>Application rate (g/ha)</b>		1 × 1890				
<b>Acute toxicity (mg/kg bw)</b>		4334				
<b>TER criterion</b>		10				
<b>Crop scenario</b>	<b>Indicator species for screening</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub> (mg/kg bw/d)</b>	<b>TER<sub>a</sub></b>	
Orchards	Small insectivorous bird	46.8	1	88.45	49.0	
<b>Reprod. toxicity (mg/kg bw/d)</b>		96.3				
<b>TER criterion</b>		5				
<b>Crop scenario</b>	<b>Indicator species for screening</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>lt</sub></b>	
Orchards	Small insectivorous bird	18.2	1 x 0.53	18.23	5.3	



SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.2-4: Screening assessment of the acute risk for birds and screening and first-tier assessment of the long-term/reproductive risk for birds due to the use of CANDELA in winter wheat (desiccation)**

Intended use		Winter wheat (desiccation)				
Active substance/product		Glyphosate				
Application rate (g/ha)		1 × 1080				
Acute toxicity (mg/kg bw)		4334				
TER criterion		10				
Crop scenario	Indicator species for screening	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Cereals	Small omnivorous bird	158.8	1	171.50	25.3	
Reprod. toxicity (mg/kg bw/d)		96.3				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Cereals	Small omnivorous bird	64.8	1 x 0.53	37.09	2.6	
Cereals late post-emergence (May-june) BBCH 71-89	Small insectivorous bird “passerine”	22.4	1 x 0.53	12.82	7.5	
Cereals late season-seed heads	Small granivorous/insectivorous bird “bunting”	4.7	1 x 0.53	2.69	35.8	
Cereals BBCH ≥ 40	Small omnivorous bird “lark”	3.3	1 x 0.53	1.89	51.0	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.2-5: Screening assessment of the acute risk for birds and screening and first-tier assessment of the long-term/reproductive risk for birds due to the use of CANDELA in grapevine**

Intended use		Grapevine				
Active substance/product		Glyphosate				
Application rate (g/ha)		1 × 1890				
Acute toxicity (mg/kg bw)		4334				
TER criterion		10				
Crop scenario	Indicator species for screening	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub>	TER <sub>a</sub>	
Growth stage				(mg/kg bw/d)		
Vineyard	Small omnivorous bird	95.3	1	180.12	24.1	

<b>Reprod. toxicity (mg/kg bw/d)</b>		96.3			
<b>TER criterion</b>		5			
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>lt</sub></b>
Vineyard	Small omnivorous bird	38.9	1 x 0.53	38.97	<b>2.5</b>
Vineyard BBCH 10-19	Small granivorous bird “Finch”	6.9	1 x 0.53	6.91	13.9
Vineyard BBCH 20-39	Small granivorous bird “Finch”	5.7	1 x 0.53	5.71	16.9
Vineyard BBCH ≥ 40	Small granivorous bird “Finch”	3.4	1 x 0.53	3.41	28.3
Vineyard BBCH 10-19	Small insectivorous species “Redstart”	11.5	1 x 0.53	11.52	8.4
Vineyard BBCH ≥ 20	Small insectivorous species “Redstart”	9.9	1 x 0.53	9.92	9.7
Vineyard BBCH 10-19	Small omnivorous bird “lark”	6.5	1 x 0.53	6.51	14.8
Vineyard BBCH 20-39	Small omnivorous bird “lark”	5.4	1 x 0.53	5.41	17.8
Vineyard BBCH ≥ 40	Small omnivorous bird “lark”	3.3	1 x 0.53	3.31	29.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

## Conclusion

According to the screening and first tier assessments, all the TER<sub>a</sub> and TER<sub>lt</sub> values for the active substance Glyphosate are greater than the ~~Annex VI~~ trigger of 10 and 5, respectively, indicating that CANDELA presents no unacceptable acute and long-term risk to birds according to the intended uses.

### 9.2.2.2 Higher-tier risk assessment

Not required

### 9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

#### Leaf scenario

Since CANDELA is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

#### Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less

sorptive substances ( $K_{oc} < 500 \text{ L/kg}$ ) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500 \text{ L/kg}$ ).

With a  $K(f)_{oc}$  of 15388 (arithmetic mean,  $n = 20$ ; EFSA Journal 2015;13(11):4302) Glyphosate belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “all crops” also covers the risk for birds from all other intended uses (see 9.1.2).

Effective application rate (g/ha) =	1890		
Acute toxicity (mg/kg bw) =	4334	quotient =	0.44
Reprod. toxicity (mg/kg bw/d) =	96.3	quotient =	19.63

As the ratios do not exceed the value of 3000 for glyphosate, it is not necessary to conduct a drinking water risk assessment for birds.

#### 9.2.2.4 Effects of secondary poisoning

The  $\log P_{ow}$  of Glyphosate and its metabolite was  $< 3$  and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

#### Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

#### Risk assessment for fish-eating birds via secondary poisoning

Not required.

#### 9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

#### 9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

#### 9.2.4 Overall conclusions

All the  $TER_a$  and  $TER_{lt}$  values for the active substance Glyphosate are greater than the ~~Annex VI~~ trigger of 10 and 5, respectively, indicating that CANDELA presents no unacceptable acute and long-term risk to birds according to the intended uses.

#### Review Comments:

The acute and chronic risks of CANDELA to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredient and maximum residues occurring on food items. No acute toxicity test with the formulation was required.

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

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

### 9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

#### 9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Glyphosate and its relevant metabolite. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of CANDELA were not evaluated as part of the EU assessment of Glyphosate.

However, the provision of further data on the CANDELA is not considered essential, because active substance data on toxicity to mammals can be used and additional formulation data are not considered essential.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals**

Species	Substance	Exposure System	Results	Reference
Rat	Glyphosate	Acute	LD <sub>50</sub> > 2000 mg/kg bw	EFSA Journal 2015;13(11):4302
Rat	Glyphosate	Long term	NOAEL = 197 mg/kg bw/d	EFSA Journal 2015;13(11):4302
Rabbit	Glyphosate	Long term	NOAEL = 50 mg/kg bw	EFSA Journal 2015;13(11):4302

##### 9.3.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

#### 9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil and grassland also covers the risk for mammals from all other intended uses before seedling in groups bare soil and the assessment for the use group orchards and grapevine also covers the risk for mammals from all other intended uses in groups orchards (see 9.1.2). In addition, the use grapevine and winter wheat for desiccation have also been assessed separately.

##### 9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

**Table 9.3-2: Screening and First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CANDELA in grassland and bare soil (before seedling of winter cereals, oilseed rape, spring barley, sunflower and maize)**

<b>Intended use</b>		Bare soil before seedling (winter cereals, oilseed rape, spring barley, sunflower and maize)			
<b>Active substance/product</b>		Glyphosate			
<b>Application rate (g/ha)</b>		1 × 1890			
<b>Acute toxicity (mg/kg bw)</b>		2000			
<b>TER criterion</b>		10			
<b>Crop scenario</b>	<b>Indicator species for screening</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub></b> (mg/kg bw/d)	<b>TER<sub>a</sub></b>
Growth stage					
Bare soil	Small granivorous mammal	14.4	1	27.22	73.5
Grassland	Small granivorous mammal	136.4	1	258.8	<b>7.7</b>
Grassland All season	Large herbivorous mammal 'lagomorph'	32.6	1	61.61	32.5
Grassland late	Small herbivorous mammal 'shrew'	5.4	1	10.21	195.9
Grassland All season	Small herbivorous mammal 'vole'	136.4	1	258.8	<b>7.7</b>
Grassland Late season	Small omnivorous mammal 'mouse'	14.4	1	27.22	73.5
<b>Reprod. toxicity (mg/kg bw/d)</b>		50			
<b>TER criterion</b>		5			
<b>Crop scenario</b>	<b>Indicator species for screening</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub></b> (mg/kg bw/d)	<b>TER<sub>lt</sub></b>
Growth stage					
Bare soil	Small granivorous mammal	6.6	1 x 0.53	6.61	7.6
Grassland	Small herbivorous mammal	72.3	1 x 0.53	72.42	<b>0.7</b>
Grassland All season	Large herbivorous mammal 'lagomorph'	17.3	1 x 0.53	17.33	<b>2.9</b>
Grassland late	Small herbivorous mammal 'shrew'	1.9	1 x 0.53	1.9	26.3
Grassland All season	Small herbivorous mammal 'vole'	72.3	1 x 0.53	72.33	<b>0.7</b>
Grassland Late season	Small omnivorous mammal 'mouse'	6.6	1 x 0.53	6.61	7.6

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-3: Screening and First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CANDELA in grassland (before seedling of winter cereals, oilseed rape, spring barley, sunflower and maize)**

Intended use		Before seedling (winter cereals, oilseed rape, spring barley, sunflower and maize)				
Active substance/product		Glyphosate				
Application rate (g/ha)		1 × 1080				
Acute toxicity (mg/kg bw)		2000				
TER criterion		10				
Crop scenario	Indicator species for screening	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Grassland	Small herbivorous mammal	136.4	1	147.31	13.6	
Reprod. toxicity (mg/kg bw/d)		50				
TER criterion		5				
Crop scenario	Indicator species for screening	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Grassland	Small granivorous mammal	72.3	1 x 0.53	41.38	1.2	
Grassland All season	Large herbivorous mammal ‘lagomorph’	17.3	1 x 0.53	9.90	5.05	
Grassland late	Small herbivorous mammal ‘shrew’	1.9	1 x 0.53	1.09	45.9	
Grassland All season	Small herbivorous mammal ‘vole’	72.3	1 x 0.53	41.38	1.2	
Grassland Late season	Small omnivorous mammal ‘mouse’	6.6	1 x 0.53	3.78	13.2	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-4: Screening assessment of the acute and screening and first-tier assessment of the long-term/reproductive risk for mammals due to the use of CANDELA in Orchards (pome/stone fruits)**

Intended use		Orchards (pome/stone fruits)				
Active substance/product		Glyphosate				
Application rate (g/ha)		1 × 1890				
Acute toxicity (mg/kg bw)		> 2000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Orchard	Small herbivorous mammal	136.4	1	257.80	> <b>7.8</b>	
Orchard application not crop directed	Large herbivorous mammal “lagomoprh”	35.1	1	66.34	> 30.1	
Orchard application not crop directed	Small herbivorous mammal “vole”	136.4	1	257.80	> <b>7.8</b>	
Orchard application not crop directed	Small insectivorous mammal “shrew”	5.4	1	10.21	> 196.0	

Orchard application not crop directed	Small omnivorous mammal “mouse”	17.2	1	32.51	> 61.5
<b>Reprod. toxicity (mg/kg bw/d)</b>		50			
<b>TER criterion</b>		5			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>
Orchard	Small herbivorous mammal	72.3	1 x 0.53	72.42	<b>0.7</b>
Orchard application not crop directed	Large herbivorous mammal “lagomoprh”	14.3	1 x 0.53	14.32	<b>3.5</b>
Orchard application not crop directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	72.42	<b>0.7</b>
Orchard application not crop directed	Small insectivorous mammal “shrew”	1.9	1 x 0.53	1.90	26.3
Orchard application not crop directed	Small omnivorous mammal “mouse”	7.8	1 x 0.53	7.81	6.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-5: Screening and First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CANDELA in Orchards (pome/stone fruits)**

<b>Intended use</b>		Orchards (pome/stone fruits)			
<b>Active substance/product</b>		Glyphosate			
<b>Application rate (g/ha)</b>		1 × 1080			
<b>Acute toxicity (mg/kg bw)</b>		> 2000			
<b>TER criterion</b>		10			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>
Orchard	Small herbivorous mammal	136.4	1	147.31	>13.6
<b>Reprod. toxicity (mg/kg bw/d)</b>		50			
<b>TER criterion</b>		5			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>
Orchard	Small herbivorous mammal	72.3	1 x 0.53	41.38	<b>1.2</b>
Orchard application not crop directed	Large herbivorous mammal “lagomoprh”	14.3	1 x 0.53	8.19	6.1
Orchard application not crop directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	41.38	<b>1.2</b>
Orchard application not crop directed	Small insectivorous mammal “shrew”	1.9	1 x 0.53	1.09	45.9
Orchard application not crop directed	Small omnivorous mammal “mouse”	7.8	1 x 0.53	4.46	11.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-6: Screening assessment of the acute and screening and first-tier assessment of the long-term/reproductive risk for mammals due to the use of CANDELA in winter wheat (desiccation)**

Intended use		Winter wheat (desiccation)				
Active substance/product		Glyphosate				
Application rate (g/ha)		1 × 1080				
Acute toxicity (mg/kg bw)		> 2000				
TER criterion		10				
Crop scenario	Indicator species for screening	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Cereals	Small herbivorous mammal	118.4	1	127.87	> 15.6	
Reprod. toxicity (mg/kg bw/d)		50				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Cereals	Small herbivorous mammal	48.3	1 x 0.53	27.65	1.8	
Cereals BBCH ≥ 20	Small insectivorous mammal “shrew”	1.9	1 x 0.53	1.09	46.0	
Cereals BBCH ≥ 40	Small herbivorous mammal “vole”	21.7	1 x 0.53	12.42	4.0	
Cereals BBCH ≥ 40	Small omnivorous mammal “mouse”	2.3	1 x 0.53	1.32	38.0	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-7: Screening and First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CANDELA in grapevine**

<b>Intended use</b>		Grapevine				
<b>Active substance/product</b>		Glyphosate				
<b>Application rate (g/ha)</b>		1 × 1890				
<b>Acute toxicity (mg/kg bw)</b>		> 2000				
<b>TER criterion</b>		10				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub></b> (mg/kg bw/d)	<b>TER<sub>a</sub></b>	
Vineyard	Small insectivorous mammal	136.4	1	257.80	> <b>7.8</b>	
Vineyard application ground directed	Large herbivorous mammal “lagomoprh”	27.2	1	51.41	> 38.9	
Vineyard BBCH 10-19	Large herbivorous mammal “lagomoprh”	16.3	1	30.81	>64.9	
Vineyard BBCH 20-39	Large herbivorous mammal “lagomoprh”	13.6	1	25.70	>77.8	
Vineyard BBCH ≥ 40	Large herbivorous mammal “lagomoprh”	8.1	1	15.31	>130.6	



Vineyard BBCH 10-19	Small insectivorous mammal “shrew”	7.6	1	14.36	>139.2
Vineyard BBCH ≥ 20	Small insectivorous mammal “shrew”	5.4	1	10.21	>196.0
Vineyard application ground directed	Small herbivorous mammal “vole”	136.4	1	257.80	> <b>7.8</b>
Vineyard BBCH 10-19	Small herbivorous mammal “vole”	81.9	1	154.79	>12.9
Vineyard BBCH 20-39	Small herbivorous mammal “vole”	68.2	1	128.9	>15.5
Vineyard BBCH ≥ 40	Small herbivorous mammal “vole”	40.9	1	77.30	>25.9
Vineyard application ground directed	Small omnivorous mammal “mouse”	17.2	1	32.51	> 61.5
Vineyard BBCH 10-19	Small omnivorous mammal “mouse”	10.3	1	19.47	>102.7
Vineyard BBCH 20-39	Small omnivorous mammal “mouse”	8.6	1	16.25	>123.0
Vineyard BBCH ≥ 40	Small omnivorous mammal “mouse”	5.2	1	9.83	>203.5
<b>Reprod. toxicity (mg/kg bw/d)</b>		50			
<b>TER criterion</b>		5			
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>it</sub></b>
Vineyard	Small insectivorous mammal	72.3	1 x 0.53	72.42	<b>0.7</b>
Vineyard application ground directed	Large herbivorous mammal “lagomoprh”	11.1	1 x 0.53	11.12	<b>4.5</b>
Vineyard BBCH 10-19	Large herbivorous mammal “lagomoprh”	6.7	1 x 0.53	6.71	7.5
Vineyard BBCH 20-39	Large herbivorous mammal “lagomoprh”	5.5	1 x 0.53	5.51	9.1
Vineyard BBCH ≥ 40	Large herbivorous mammal “lagomoprh”	3.3	1 x 0.53	3.31	15.1
Vineyard BBCH 10-19	Small insectivorous mammal “shrew”	4.2	1 x 0.53	4.21	11.9
Vineyard BBCH ≥ 20	Small insectivorous mammal “shrew”	1.9	1 x 0.53	1.90	26.3
Vineyard application ground directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	72.42	<b>0.7</b>
Vineyard BBCH 10-19	Small herbivorous mammal “vole”	43.4	1 x 0.53	43.47	1.2
Vineyard BBCH 20-39	Small herbivorous mammal “vole”	36.1	1 x 0.53	36.16	1.4
Vineyard BBCH ≥ 40	Small herbivorous mammal “vole”	21.7	1 x 0.53	21.74	2.3
Vineyard application ground directed	Small omnivorous mammal “mouse”	7.8	1 x 0.53	7.81	6.4

Vineyard BBCH 10-19	Small omnivorous mammal "mouse"	4.7	1 x 0.53	4.71	10.6
Vineyard BBCH 20-39	Small omnivorous mammal "mouse"	3.9	1 x 0.53	3.91	12.8
Vineyard BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3	1 x 0.53	2.30	21.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-8: Screening and First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CANDELA in grapevine**

Intended use		Grapevine				
Active substance/product		Glyphosate				
Application rate (g/ha)		1 × 1080				
Acute toxicity (mg/kg bw)		> 2000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Vineyard	Small insectivorous mammal	136.4	1	147.31	>13.6	
Reprod. toxicity (mg/kg bw/d)		50				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Vineyard	Small insectivorous mammal	72.3	1 x 0.53	41.38	1.2	
Vineyard application ground directed	Large herbivorous mammal “lagomoprh”	11.1	1 x 0.53	6.35	7.9	
Vineyard BBCH 10-19	Large herbivorous mammal “lagomoprh”	6.7	1 x 0.53	3.84	13.0	
Vineyard BBCH 20-39	Large herbivorous mammal “lagomoprh”	5.5	1 x 0.53	3.15	15.9	
Vineyard BBCH ≥ 40	Large herbivorous mammal “lagomoprh”	3.3	1 x 0.53	1.89	26.5	
Vineyard BBCH 10-19	Small insectivorous mammal “shrew”	4.2	1 x 0.53	2.40	20.8	
Vineyard BBCH ≥ 20	Small insectivorous mammal “shrew”	1.9	1 x 0.53	1.09	45.9	
Vineyard application ground directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	41.38	1.2	
Vineyard application ground directed	Small omnivorous mammal “mouse”	7.8	1 x 0.53	4.46	11.2	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

## Conclusion

### Bare soil

According to the screening assessments for bare soil, all the TER<sub>a</sub> and TER<sub>lt</sub> values for the active substance Glyphosate are greater than the Annex VI trigger of 10 and 5, respectively, indicating that CANDELA presents no unacceptable acute and long-term risk to mammals according to the intended uses on winter cereals, oilseed rape, spring barley, sunflower and maize.

#### Winter wheat (desiccation)

According to the first-tier assessments for winter wheat (desiccation), the TER<sub>a</sub> values are greater than the Annex VI trigger of 10 whereas TER<sub>lt</sub> values are lower than the Annex VI trigger of 5, indicating that CANDELA presents an unacceptable long-term risk to mammals. Therefore, higher-tier long-risk assessments were necessary.

#### Orchards and grapevine

According to the first-tier assessments for orchards and grapevine, all the TER<sub>a</sub> and TER<sub>lt</sub> values for the active substance Glyphosate are lower than the Annex VI trigger of 10 and 5, respectively, indicating that CANDELA presents an unacceptable acute and long-term risk to mammals.

Therefore, higher tier risk assessments were conducted only for the long term risk.

According to the first-tier assessments for orchards and grapevine, the TER<sub>a</sub> and TER<sub>lt</sub> values for the active substance Glyphosate are lower than the trigger of 10 and 5, respectively, indicating that CANDELA presents an unacceptable acute and long-term risk to mammals.

During the evaluation of the dossier, the Applicant modified the proposed use pattern of the Candela. For this reason, a risk assessment was performed for the higher dose rate of the product proposed in the original GAP. As a high acute and long-term risk has been identified, zRMS performed recalculation of TERs for the lower dose rate, currently proposed for use in grasslands (1.08 kg a.s./ha). According to the first-tier assessments for grassland, the TER<sub>a</sub> values are greater than the trigger of 10 whereas TER<sub>lt</sub> values are lower than the trigger of 5.

Therefore, higher-tier risk assessment was conducted only for the long-term risk for dose rate of 1.08 kg a.s./ha.

#### Grassland

During the evaluation of the dossier, the Applicant modified the proposed use pattern of the Candela. For this reason, a risk assessment was performed for the higher dose rate of the product proposed in the original GAP. As a high acute and long-term risk has been identified, zRMS performed recalculation of TERs for the lower dose rate, currently proposed for use before seedling (winter cereals, oilseed rape, spring barley, sunflower and maize) - grasslands (1.08 kg a.s./ha). According to the first-tier assessments for grassland, the TER<sub>a</sub> values are greater than the trigger of 10 whereas TER<sub>lt</sub> values are lower than the trigger of 5.

Therefore, higher-tier risk assessment was conducted only for the long-term risk for dose rate of 1.08 kg a.s./ha.

### **9.3.2.2 Higher-tier risk assessment**

The Tier I risk assessment showed an unacceptable acute and long-term risk for small herbivorous “vole” in grassland, orchards and grapevine, an unacceptable long-term risk for large herbivorous “lagomorph” in orchards and grapevine and an unacceptable long-term risk for small herbivorous “vole” in winter wheat (desiccation). A further higher-tier risk assessment was needed, and the following parameters were refined.

#### Application rate

The applications of CANDELA are made round base of trunk and to the intra-rows (inner strips between two trees within a row). According to the EFSA Journal 2015;13(11):4302, application rates per ha are expressed per ‘unit of treated surface area’ and the actual application rate per ha orchard or vineyard will only be 50% of the reported rate. Therefore EFSA agree that the actual application rates per hectare of cropped areas were 50% of the rates per hectare of treated areas (i.e. ~~1x0.945~~ 1x0.540 kg a.s./ha) and was

used in the refinement of the risk assessment.

#### *DT<sub>50</sub> and TWA*

In the Tier I assessment, the default foliar DT<sub>50</sub> is 10 days. However, according to the EFSA Journal 2015;13(11):4302, the refinement was based on the decline of glyphosate residue in grass as characterised using data from 22 residue trials from the monograph of Glyphosate. In the monograph of Glyphosate, residue trials were done in different countries, and the information used for the determination of the DT<sub>50</sub> is showed in tables below:

**Table 9.3-9: Glyphosate residues in grass following a single treatment**

Country, Year Trial, ID	App. Rate (kg a.s./ ha) <sup>1</sup>	NRG 100% of DM <sup>2</sup>	% of Day 0 a.s. residue	DAT <sup>3</sup>	R <sup>2</sup>	k (days- 1)	DT <sub>50</sub>	Glyphosate Monograph Reference; Monsanto Report No.
Great Britain, 1981								
SU 8125	1.08	101	100	1h	0.990	0.4106	1.7	RIP95- 01242 MLL 30.080
		27	26.7	3				
		12	11.9	7				
SU 8125	2.88	67	100	1 h	0.997	0.3251	2.1	
		27	40.3	3				
		5	7.5	7				
SU 30117	1.08	247	100	1 h	0.997	0.9587	0.72	
		14	5.7	3				
		8	3.2	7				
		7	2.8	9				
		6	2.4	10				
		3	1.2	14				
SU 30117	2.88	130	100	1 h	0.976	0.7063	0.98	
		14	10.8	3				
		11	8.5	7				
		9	6.9	9				
		10	7.7	10				
		3	2.3	14				
SU 30119	1.08	193	100.0	1 h	0.809	0.1456	4.8	
		175	90.7	4				
		38	19.7	9				
		9	4.7	11				
SU 30119	2.88	161	100.0	1 h	0.901	0.1550	4.5	
		123	76.4	4				
		30	18.6	9				
		13	8.1	11				
France, 1981								
811	0.72	168	100.0	0	0.976	0.4576	1.5	RIP95- 01245 MLL 30.082
		9	5.4	5				
		23	13.7	8				
		5	3.0	12				
811	1.08	134	100.0	0	0.950	0.3768	1.8	
		9	6.7	5				
		27	20.1	8				
		5	3.7	12				
The Netherlands, 1982								
NL 8207	1.44	682.0	100.0	0	0.998	0.4230	1.6	RIP95- 01264 MLL 30.101
		77.0	11.3	5				
		31.7	4.6	10				

Country, Year Trial, ID	App. Rate (kg a.s./ ha) <sup>1</sup>	NRG 100% of DM <sup>2</sup>	% of Day 0 a.s. residue	DAT <sup>3</sup>	R <sup>2</sup>	k (days- 1)	DT <sub>50</sub>	Glyphosate Monograph Reference; Monsanto Report No.
Denmark, 1981								
Villbach (GE)-1981- 0181Vi	1.80	162.9	100	0	0.844	0.1415	4.9	RIP95- 01273 MLL 30.132
		36	22.1	7				
		52.6	32.3	14				
Villbach (GE)-1981- 0281Vi	1.80	496.3	100	0	0.994	0.1537	4.5	
		184.4	37.2	7				
		37.0	7.5	14				
Lettgunbrun n (GE)- 1981- 0981LE	1.80	437.9	100	0	0.961	0.2616	2.6	
		51.2	11.7	7				
		69.4	15.8	14				
Villbach (GE)-1981- 0481Vi	1.80	190.7	100	0	0.937	0.1098	6.3	
		69.0	36.2	7				
		59.0	30.9	14				
Denmark, 1983								
Vogach (GE)-19B	1.44	158.9	100	0	0.995	0.9083	0.76	RIP95- 01273 MLL 30.132
		9.9	6.2	3				
		8.3	5.2	7				
		3.3	2.1	10				
		4.4	2.8	14				
Untermehlha usen (GE)- 1983	1.44	169.6	100	0	0.990	0.2852	2.4	
		16.4	9.7	7				
		16.2	9.6	10				
		13.0	7.7	14				
Schoneberg	1.44	257.2	100	0	*	*	10 <sup>4</sup>	
		155.8	60.6	3				
		144.6	56.2	7				
		123.9	48.2	10				
		151.0	58.7	14				
Utphe (GE)- 1983	1.44	354.9	100	0	0.961	0.1718	4.0	
		78.7	22.2	7				
		62.7	17.7	14				
		39.0	11.0	21				
Meiling (GE)-1983	1.44	253.9	100	0	0.997	0.9014	0.77	
		16.6	6.5	3				
		6.0	2.4	7				
		6.3	2.5	10				
		8.3	3.3	14				

<sup>1</sup> a.s. = glyphosate acid.

<sup>2</sup> NRG 100% of DM = residual glyphosate mg/kg normalised to 1 kg a.s./ha and corrected to 100% dry matter content.  
Values taken directly from Monsanto reports.

<sup>3</sup> DAT = Days After Treatment.

<sup>4</sup> Estimated DT<sub>50</sub> value based on time when approximately 50% dissipation was reached.

\* Did not fit standard 1<sup>st</sup> order dissipation model.

**Table 9.3-10: Glyphosate residues in grass following a single treatment**

App. Rate (kg a.s./ha) <sup>1</sup>	Residue (mg a.s./kg wet weight)	% of Day 0 a.s. residue	DAT <sup>3</sup>	R <sup>2</sup>	k (days-1)	DT <sub>50</sub>	Glyphosate Monograph Reference; Cheminova Report no.
2.16	237.6	100.0	4 h	0.987	1.9629	0.35	RIP95-01308 IF-93/04572-01
	45	18.9	1				
	19.6	8.2	3				
	9.6	4.0	5				
1.08	87.6	100.0	4 h	0.937	2.0879	0.33	
	14.6	16.7	1				
	14.3	16.3	3				
	8.3	9.5	5				
2.16	252.3	100.0	4 h	0.951	0.4885	1.4	
	131	51.9	1				
	72.1	28.6	3				
	36.8	14.6	5				
1.08	90.4	100.0	4 h				
	142.8	158.0	1				
	39.8	44.0	3				
	17.3	19.1	5				
	16.6	6.5	3				
	6.0	2.4	7				
	6.3	2.5	10				
	8.3	3.3	14				

<sup>1</sup> a.s. = glyphosate acid.

<sup>2</sup> DAT = Days After Treatment.

<sup>3</sup> Estimated DT<sub>50</sub> value based on time when approximately 50% dissipation was reached.

\* Did not fit standard 1<sup>st</sup> order dissipation model.

The average DT<sub>50</sub> for the 22 trials was **2.8 days** and the refined 21-day twa value was calculated to be **0.19**, and they were used in the refinement of the risk assessment.

#### RUD

To refine risk for small herbivorous “vole”, residue values were used. As report in Dithianon RAR, residue trials were available in winter barley and winter soft wheat for Northern EU region.

In the following table are summarized residue trials suitable to refine risk assessment.

**Table 9.3-3: Residue trials suitable to refine mammals risk assessment**

Report No. Location incl. Postal code and date	Crop	Commodity/ Variety	Application rate per treatment			Growth stage at last treatment or date	Portion analysed	Residue Day 0 (mg/kg)	RUD
			kg a.i./ha	Water l/ha	kg a.i./hl				
FSG-0606, trial 1 Germany 04668 Mötterwitz 2007-09-26	Winter Barley	Lomerid (lodged grain)	1.85	308	0.60	BBCH 87	Rest of plant	34	18.34

Report No. Location incl. Postal-code and date	Crop	Commodity/ Variety	Application rate per treatment			Growth stage at last treatment or date	Portion analysed	Residue Day 0 (mg/kg)	RUD
			kg a.i./ha	Water l/ha	kg a.i./hl				
IF-93/04573-01; AS/1905/CN; 01 United Kingdom (UK) SK412237 Wilson; Derbyshire 1992-02-10	Winter Barley	Magie	1.4	200	0.72	BBCH 89- 92	Plant	77.9	55.64
IF-93/04573-01; AS/1905/CN; 02 United Kingdom (UK) SK412237 Wilson; Derbyshire 1992-02-10	Winter Barley	Magie	0.72	200	0.36	BBCH 89- 92	Plant	58.6	81.39
IF-93/04573- 01; AS/1905/CN; 03 United Kingdom (UK) SK412237 Wilson; Derbyshire 1992-02-10	Winter Barley	Magie	0.72	200	0.36	BBCH 89- 92	Plant	24.9	34.58
IF-93/04573- 01; AS/1905/CN; 04 United Kingdom (UK) SK412237 Wilson; Derbyshire 1992-02-10	Winter Barley	Magie	0.36	200	0.18	BBCH 89- 92	Plant	8.0	22.22
AS/1906/CN; trial AS/1906/CN/1, plot 2 United Kingdom SK 409-245 Derbyshire 1993-01-29	Winter Soft Wheat	Riband	1.4	200	0.72	BBCH 91	whole plant	43.6	31.14

Report No. Location incl. Postal-code and date	Crop	Commodity/ Variety	Application rate per treatment			Growth stage at last treatment or date	Portion analysed	Residue Day 0 (mg/kg)	RUD
			kg a.i./ha	Water l/ha	kg a.i./hl				
AS/1906/CN, trial AS/1906/CN/1, plot 3 United Kingdom SK 409 245 Derbyshire 1993-01-29	Winter Soft Wheat	Riband	0.72	200	0.36	BBCH 91	whole plant	26.5	36.81
AS/1906/CN, trial AS/1906/CN/1, plot 4 United Kingdom SK 409 245 Derbyshire 1993-01-29	Winter Soft Wheat	Riband	0.72	200	0.36	BBCH 91	whole plant	11.1	15.42
AS/1906/CN, trial AS/1906/CN/1, plot 5 United Kingdom SK 409 245 Derbyshire 1993-01-29	Winter Soft Wheat	Riband	0.36	200	0.18	BBCH 91	whole plant	12.5	34.72
								mean	36.70
								90th %ile	60.79
								SD	20.60

The 90<sup>th</sup> percentile value of RUD was 60.79 and the mean value was 36.70. For the refinement of acute risk, the 90<sup>th</sup> percentile value of 60.79 was used and for the long term risk the mean value of 36.70 was used.



**Table 9.3-11:** Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of CANDELA in Orchards (pome/stone fruits) and Vineyard – refined parameters (\*) are further described and justified in the text

Intended use	Orchards (pome/stone fruits)						
Active substance/product	Glyphosate						
Application rate (g/ha)	1 × 1890 (1 × 0.945*)						
Acute toxicity (mg/kg bw)	>2000						
TER criterion	10						
Focal species	Food category, % in diet	FIR/bw	RUD <sup>90th</sup> × DF (mg/kg food)	MAF	PT	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>
Common vole ( <i>Microtus arvalis</i> )	Grass + cereals	1.33	60.79 <sup>1</sup> × 1	1.0	1.0	76.40	26.18
Reprod. toxicity (mg/kg bw/d)	50						
TER criterion	5						
Focal species	Food category, % in diet	FIR/bw	RUD <sub>m</sub> × DF (mg/kg food)	MAF <sub>m</sub> × TWA <sup>*</sup>	PT	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>
Rabbit ( <i>Oryctolagus cuniculus</i> )	100% Non-grass herbs	0.50	28.7 <sup>2</sup> × 1	1.0 × 0.53	1.0	7.19	6.96
Common vole ( <i>Microtus arvalis</i> )	100% grass (grass+cereals)	1.33	36.70 <sup>1</sup> × 1	1.0 × 0.19 <sup>3</sup>	1.0	8.76	5.71

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> 90<sup>th</sup> percentile and mean value obtained from 9 residue trials in winter barley and winter wheat (please refer to the RAR of Glyphosate Volume 3, Annex B.7, Residues data, 2013).

<sup>2</sup> According to Appendix A of EFSA/2009/1438.

<sup>3</sup> Value of ftwa obtained from calculated DT<sub>50</sub> from decline residue trials in grass (please refer to the Final addendum to the Renewal Assessment Report of Glyphosate, October 2015).

Intended use	Orchards (pome/stone fruits) and Vineyard					
Active substance/product	Glyphosate					
Application rate (g/ha)	1 × 0.54*					
Reprod. toxicity (mg/kg bw/d)	50					
TER criterion	5					
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>	
Orchard application not crop directed	Small herbivorous mammal “vole”	72.3	1 × 0.19*	7.42	6.7	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-4: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of CANDELA in winter wheat (desiccation) – refined parameters (\*) are further described and justified in the text**

<b>Intended use</b>		Winter wheat (desiccation)					
<b>Active substance/product</b>		Glyphosate					
<b>Application rate (g/ha)</b>		1 × 1080 (1 × 0.945*)					
<b>Reprod. toxicity (mg/kg bw/d)</b>		50					
<b>TER criterion</b>		5					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>m</sub><sup>§</sup> × DF</b> (mg/kg food)	<b>MAF<sub>m</sub> × TWA<sup>§</sup></b>	<b>PT</b>	<b>DDD<sub>m</sub></b> (mg/kg bw/d)	<b>TER<sub>it</sub></b>
Common vole ( <i>Microtus arvalis</i> )	100% grass (grass+cereals)	1.33	36.70 <sup>1</sup> × 1	1.0 × 0.19 <sup>2</sup>	1.0	5.01	9.98

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> Mean value obtained from 9 residue trials in winter barley and winter wheat (please refer to the RAR of Glyphosate Volume 3, Annex B.7, Residues data, 2013).

<sup>2</sup> Value of ftwa obtained from calculated DT<sub>50</sub> from decline residue trials in grass (please refer to the Final addendum to the Renewal Assessment Report of Glyphosate, October 2015).

<b>Intended use</b>		Winter wheat (desiccation)				
<b>Active substance/product</b>		Glyphosate				
<b>Application rate (g/ha)</b>		1 × 1.08				
<b>Reprod. toxicity (mg/kg bw/d)</b>		50				
<b>TER criterion</b>		5				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub></b> (mg/kg bw/d)	<b>TER<sub>it</sub></b>	
Cereals BBCH ≥ 40	Small herbivorous mammal “vole”	21.7	1 × 0.19*	4.45	11.2	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-13: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of CANDELA in grapevine grassland – refined parameters (\*) are further described and justified in the text**

<b>Intended use</b>		Grapevine					
<b>Active substance/product</b>		Glyphosate					
<b>Application rate (g/ha)</b>		1 × 1890 (1 × 0.945*)					
<b>Acute toxicity (mg/kg bw)</b>		≥ 2000					
<b>TER criterion</b>		10					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>m</sub><sup>§</sup> × DF</b> (mg/kg food)	<b>MAF</b>	<b>PT</b>	<b>DDD<sub>m</sub></b> (mg/kg bw/d)	<b>TER<sub>it</sub></b>
Common vole ( <i>Microtus arvalis</i> )	Grass + cereals	1.33	60.79 <sup>1</sup> × 1	1.0	1.0	76.40	26.18
<b>Reprod. toxicity (mg/kg bw/d)</b>		50					

TER criterion		5						
Focal species	Food category, % in diet	FIR/bw	$RUD_m \times DF$ (mg/kg food)	$MAF_m \times TWA$	PT	$DDD_m$ (mg/kg bw/d)	$TER_{it}$	
Rabbit ( <i>Oryctolagus cuniculus</i> )	100% Plant matter	0.39	$28.7^2 \times 1$	$1.0 \times 0.53$	1.0	5.61	8.92	
Common vole ( <i>Microtus arvalis</i> )	100% grass (grass+cereals)	1.33	$36.70^1 \times 1$	$1.0 \times 0.19^3$	1.0	8.76	5.71	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Before seedling (winter cereals, oilseed rape, spring barley, sunflower and maize)				
Active substance/product		Glyphosate				
Application rate (g/ha)		1 × 1080				
Reprod. toxicity (mg/kg bw/d)		50				
TER criterion		5				
Crop scenario	Indicator species for screening	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Grassland	Small herbivorous mammal	72.3	1 x 0.19	14.84	3.4	
All season	‘vole’					

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

For glyphosate, there is no single agreed endpoint at the zone level. Currently, some assessments are made using the endpoint of 50 mg/kg bw/d, and others with 75 mg a.s./kg bw/d. In the opinion of zRMS, the selection of a NOAEL of 50 mg/kg bw/d is considered overly conservative due to dose spacing in the study by Brooker (1991). The availability of an unusually high number of developmental toxicity studies with rabbits (7) has to be considered.

The highest NOAEL below all LOAEL values for the more sensitive endpoint parameters – maternal effects – is 75 mg/kg bw/d. This endpoint is considered protective of developmental effects.

Therefore, a refined the NOAEL of 75 mg/kg bw/d is considered relevant for use in the long-term mammalian risk assessment. Thus, additional calculation is presented below.

**Table 9.3-14: Higher tier reproductive risk to small herbivorous mammal “vole”**

Intended use		Before seedling (winter cereals, oilseed rape, spring barley, sunflower and maize)				
Active substance/product		Glyphosate				
Application rate (g/ha)		1 × 1080				
Reprod. toxicity (mg/kg bw/d)		75				
TER criterion		5				
Crop scenario	Indicator species for screening	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Grassland	Small herbivorous mammal	72.3	1 x 0.19	14.84	5.05	
All season	‘vole’					

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

## Conclusion

### Winter wheat (desiccation)

The refined TER<sub>lt</sub> values are higher than the ~~Annex VI~~ trigger of 5, indicating that CANDELA presents no unacceptable long-term risk to mammals in winter wheat.

### Orchards and grapevine

The refined TER<sub>a</sub> and TER<sub>lt</sub> values are higher than the ~~Annex VI~~ trigger of ~~10~~ and 5 respectively, indicating that CANDELA presents no unacceptable acute and long-term risk to mammals in orchards and grapevine.

### Grasslands

In the Table 9.3-13 Higher-tier long-term assessment takes account field DT50 on foliage. Nevertheless, even when considering this refinement, the high risk was identified. Thus, a further evaluation was required. The Tier 2 long-term assessment takes account, beyond DT50 on foliage, the NOAEL of 75 mg a.s./kg bw/d (consideration of the results of all rabbit studies instead of the worst-case only). Considering these refinements grasslands scenario is fully acceptable.

## 9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

### Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (K<sub>oc</sub> < 500 L/kg) or 3000 in the case of more sorptive substances (K<sub>oc</sub> ≥ 500 L/kg).

With a K(f)<sub>oc</sub> of 15388 (arithmetic mean, n = 20; EFSA Journal 2015;13(11):4302), Glyphosate belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “all crops” also covers the risk for mammals from all other intended uses (see 9.1.2).

Effective application rate (g/ha)=	1890		
Acute toxicity (mg/kg bw) =	2000	quotient =	0.95
Reprod. toxicity (mg/kg bw/d) =	50	quotient =	37.80

As the ratios do not exceed the value of 3000 for glyphosate, it is not necessary to conduct a drinking water risk assessment for mammals.

## 9.3.2.4 Effects of secondary poisoning

The log P<sub>ow</sub> of Glyphosate and its metabolite amounts was < 3 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

### Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

### **Risk assessment for fish-eating mammals via secondary poisoning**

Not required.

### **9.3.2.5 Biomagnification in terrestrial food chains**

Not relevant.

### **9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed**

Not relevant.

### **9.3.4 Overall conclusions**

#### Bare soil

According to the screening assessments for bare soil, all the TER<sub>a</sub> and TER<sub>lt</sub> values for the active substance Glyphosate are greater than the Annex VI trigger of 10 and 5, respectively, indicating that CANDELA presents no unacceptable acute and long-term risk to mammals according to the intended uses on winter cereals, oilseed rape, spring barley, sunflower and maize.

#### Grasslands

In the Table 9.3-13 Higher-tier long-term assessment takes account field DT50 on foliage. Nevertheless, even when considering this refinement, the high risk was identified. Thus, a further evaluation was required. The Tier 2 long-term assessment takes account, beyond DT50 on foliage, the NOAEL of 75 mg a.s./kg bw/d (consideration of the results of all rabbit studies instead of the worst-case only). Considering these refinements grasslands scenario is fully acceptable.

#### Winter wheat (desiccation)

TER<sub>a</sub> values are greater than the trigger of 10 showing no unacceptable acute risk to mammals according to the intended uses winter wheat (desiccation). However, TER<sub>lt</sub> values are greater than the trigger of 5 except for the species “vole”. A further refinement of the long-term risk was needed. A refinement of the risk was done by refining of application rate, DT<sub>50</sub>, ftwa and RUD, and the TER values is above the trigger showing no risk for mammals for Glyphosate in winter wheat.

#### Orchards and grapevine

TER<sub>a</sub> and TER<sub>lt</sub> values are greater than the trigger of 10 and 5 respectively, except for the species “vole” in acute and long-term risk assessment and “lagomoroph” in long-term risk assessment. A further refinement of the acute and long-term risk was needed. A refinement of the risk was done by refining of application rate, DT<sub>50</sub>, ftwa and RUD, and the TER values is above the trigger showing no risk for mammals for Glyphosate in orchards and grapevine.

No risk from drinking water neither due to secondary poisoning was expected.

#### **Review Comment:**

Based on the risk assessment for mammals performed above, the safe use was confirmed for all proposed uses of CANDELA indicated in the GAP table of this report.

The acceptability of the revised endpoint used in the higher-tier long-term assessment for uses before seedling should be reviewed at national level.

## 9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data available.

## 9.5 Effects on aquatic organisms (KCP 10.2)

### 9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Glyphosate and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of CANDELA were not evaluated as part of the EU assessment of Glyphosate.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Glyphosate and relevant metabolites**

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Glyphosate acid	96 h, s	EC <sub>50</sub> = 38 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Lepomis macrochirus</i>	Glyphosate acid	96 h, s	EC <sub>50</sub> = 47 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Danio rerio</i>	Glyphosate acid	96 h, ss	EC <sub>50</sub> = 123 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Cyprinus carpio</i>	Glyphosate acid	96 h, ss	EC <sub>50</sub> > 100 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Oncorhynchus mykiss</i>	AMPA	96 h, s	EC <sub>50</sub> = 520 mg a.s./L <sub>mm</sub>	EFSA Journal 2015;13(11):4302
<i>Pimephales promelas</i>	Glyphosate acid	255 d	NOECr = 25.7 mg a.s./L <sub>mm</sub>	EFSA Journal 2015;13(11):4302
<i>Brachydanio rerio</i>	Glyphosate acid	168 h	NOECr = 1 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Oncorhynchus mykiss</i>	Glyphosate acid	85 d	NOECr = 9.6 mg a.s./L <sub>mm</sub>	EFSA Journal 2015;13(11):4302
<i>Pimephales promelas</i>	AMPA	33 d	NOECr = 12 mg a.s./L <sub>mm</sub>	EFSA Journal 2015;13(11):4302
<i>Daphnia magna</i>	Glyphosate acid	48 h, s	EC <sub>50</sub> = 40 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Daphnia magna</i>	AMPA	48 h, s	EC <sub>50</sub> = 690 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Daphnia magna</i>	HMPA	48 h, s	EC <sub>50</sub> > 100 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Daphnia magna</i>	Glyphosate acid	21 d, ss	NOECrep = 12.5 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	AMPA	21 d, ss	NOECrep = 15 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Anabaena flosaquae</i>	Glyphosate acid	72 h, s	ErC <sub>50</sub> = 22 mg a.s./L <sub>nom</sub> EbC <sub>50</sub> = 8.5 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Skeletonema costatum</i>	Glyphosate acid	72 h, s	ErC <sub>50</sub> = 18 mg a.s./L <sub>nom</sub> EbC <sub>50</sub> = 11 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Pseudokirchneriella subcapitata</i>	Glyphosate acid	72 h, s	ErC <sub>50</sub> = 19 mg a.s./L <sub>nom</sub> EbC <sub>50</sub> = 18 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Desmodesmus subspicatus</i>	AMPA	72 h, s	ErC <sub>50</sub> = 452 mg a.s./L <sub>nom</sub> EbC <sub>50</sub> = 89.8 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Pseudokirchneriella subcapitata</i>	AMPA	72 h, s	ErC <sub>50</sub> = 200 mg a.s./L <sub>nom</sub> EbC <sub>50</sub> = 110 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Pseudokirchneriella subcapitata</i>	HMPA	72 h, s	ErC <sub>50</sub> > 115 mg a.s./L <sub>nom</sub> EbC <sub>50</sub> > 115 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Lemna gibba</i>	Glyphosate acid	14 d, ss	EC <sub>50</sub> frond = 12 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Myriophyllum aquaticum</i>	MON 52276 (acid equivalent)	14 d, s	ErC <sub>50</sub> = 4.44 mg a.s./L <sub>nom</sub> relative increase, fresh weight EC <sub>50</sub> = 12.3 mg/L growth rate, dry weight ErC <sub>50</sub> = 18.0 mg/L	EFSA Journal 2015;13(11):4302
<i>Myriophyllum aquaticum</i>	AMPA	14 d, s	EC <sub>50</sub> root length = 31.1 mg a.s./L <sub>mm</sub>	EFSA Journal 2015;13(11):4302
<i>Lemna gibba</i>	HMPA	7 d, ss	EC <sub>50</sub> frond > 123 mg a.s./L <sub>nom</sub>	EFSA Journal 2015;13(11):4302
<i>Oncorhynchus mykiss</i>	Glyphosate 54% SL	96 h, s	LC <sub>50</sub> / 96 h >250 mg fp (>135 mg as)/L	Sadananda TS, 2019, BIO-ETX 036
<i>Daphnia magna</i>	Glyphosate 54% SL	48 h, s	EC <sub>50</sub> / 48 h >100 mg fp/L	Nimal Christudas IVS, 2019, 18-208-G
<i>Pseudokirchneriella subcapitata</i>	Glyphosate 54% SL	96 h, s	ErC <sub>50</sub> >100 mg fp (>44.29 mg as)/L EyC <sub>50</sub> >100 mg fp (>44.29 mg as)/L	Nimal Christudas IVS, 2019, 18-207-G
<i>Lemna gibba</i>	Glyphosate 54% SL	7 d, s	Frond number	Nimal Christudas

Species	Substance	Exposure System	Results	Reference
			$E_r C_{50} = 61.86 \text{ mg fp}$ $(27.40 \text{ mg as})/L$ $E_y C_{50} = 39.05 \text{ mg fp}$ $(17.30 \text{ mg as})/L$ Biomass: $E_r C_{50} = 29.53 \text{ mg fp}$ $(13.08 \text{ mg as})/L$ $E_y C_{50} = 24.80 \text{ mg fp}$ $(10.98 \text{ mg as})/L$	IVS, 2019, 18-210-G

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

### 9.5.1.1 Justification for new endpoints

There is not deviation from the EU agreed endpoints.

### 9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1 and 2  $PEC_{sw}$  for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

To achieve a concise risk assessment, the risk envelope approach is applied. ~~Here, the assessment for the use group winter cereals also covers the risk for aquatic organisms from all other intended uses in oilseed rape, spring barley, winter cereals, sunflower, maize, pome fruit, grapevine and stone fruit (see Part B8).~~



In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC<sub>SW</sub>, PEC<sub>SED</sub>) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

**Table 9.5-2: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Glyphosate for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in winter cereals, spring cereals, winter and spring oilseed rape, sunflower, maize, pome fruits and grapevine (hand application to crop < 50 cm)**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Brachydanio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Skeletonema costatum</i>	<i>Myriophyllum aquaticum</i>	<i>L. gibba</i>
Endpoint (µg/L)		EC <sub>50</sub> 38000	NOEC 1000	EC <sub>50</sub> 40000	NOEC 12500	E <sub>r</sub> C <sub>50</sub> 18000	E <sub>b</sub> C <sub>50</sub> 4440	EC <sub>50</sub> 12000
AF		100	10	100	10	10	10	10
RAC (µg/L)		380	100	400	1250	1800	444	1200
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)							
<b>Step 1</b>								
-	45.86	0.121	0.459	0.115	0.037	0.025	0.103	0.038
<b>Step 2</b>								
S-Europe	17.38	0.046	0.174	0.043	0.014	0.010	0.039	
N-Europe								

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Glyphosate for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in spring cereals**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
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Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Brachydanio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Skeletonema costatum</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub> 38000	NOEC 1000	EC <sub>50</sub> 40000	NOEC 12500	EC <sub>50</sub> 18000	EC <sub>50</sub> 4440
AF		100	10	100	10	10	10
RAC (µg/L)		380	100	400	1250	1800	444
FOCUS Scenario	PEC <sub>calc</sub> (µg/L)						
Step 1							
	45.86	0.124	0.459	0.115	0.037	0.025	0.103
Step 2							
S-Europe	17.38	0.046	0.174	0.043	0.014	0.010	0.039
N-Europe							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Glyphosate for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in winter oilseed rape

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Brachydanio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Skeletonema costatum</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub> 38000	NOEC 1000	EC <sub>50</sub> 40000	NOEC 12500	EC <sub>50</sub> 18000	EC <sub>50</sub> 4440
AF		100	10	100	10	10	10

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Brachydanio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Skeletonema costatum</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub> 38000	NOEC 1000	EC <sub>50</sub> 40000	NOEC 12500	EC <sub>50</sub> 18000	EC <sub>50</sub> 4440
AP		100	10	100	10	10	10
RAC (µg/L)		380	100	400	1250	1800	444
FOCUS Scenario	PEC <sub>gt-max</sub> (µg/L)						
Step 1							

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Inverteb.-prolonged	Algae	Aquatic plants
	45-86	0.121	0.450	0.115	0.037	0.025	0.103
Step 2							
S-Europe	17-38	0.046	0.174	0.043	0.014	0.010	0.039
N-Europe							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Glyphosate for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in sunflower

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Inverteb.-prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Brachydanio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Skeletonema costatum</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub> 38000	NOEC 1000	EC <sub>50</sub> 40000	NOEC 12500	E <sub>r</sub> C <sub>50</sub> 18000	E <sub>p</sub> C <sub>50</sub> 4440
AF		100	10	100	10	10	10
RAC (µg/L)		380	100	400	1250	1800	444
FOCUS Scenario	PEC <sub>95</sub> max (µg/L)						
Step 1							
	45-86	0.121	0.450	0.115	0.037	0.025	0.103
Step 2							
S-Europe	17-38	0.046	0.174	0.043	0.014	0.010	0.039
N-Europe							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Glyphosate for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in maize**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Brachydanio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Skeletonema costatum</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>
AE		38000	1000	40000	12500	18000	4440
RAC (µg/L)		100	10	100	10	10	10
FOCUS Scenario	PEC <sub>gl</sub> maiz (µg/L)	380	100	400	1250	1800	444
Step 1							
	45-86	0.124	0.459	0.115	0.037	0.025	0.103
Step 2							
S-Europe	17-38	0.046	0.174	0.043	0.014	0.010	0.039
N-Europe							

AE: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Glyphosate for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in pome fruits and grapevine (hand application to crop < 50 cm)**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Brachydanio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Skeletonema costatum</i>	<i>Myriophyllum aquaticum</i>
Endpoint		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
(µg/L)		38000	1000	10000	12500	18000	4440
AF		100	10	100	10	10	10
RAC (µg/L)		380	100	400	1250	1800	444
FOCUS Scenario	PEC <sub>gl</sub> mus (µg/L)						
Step-1							
	45-86	0.124	0.459	0.115	0.037	0.025	0.103
Step-2							
S-Europe	17-38	0.046	0.174	0.043	0.014	0.010	0.039
N-Europe							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

## Metabolites

**Table 9.5-3:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Step 1 and 2 calculations for the use of CANDELA in winter cereals, spring cereals, winter and spring oilseed rape, sunflower, maize, pome fruits and grapevine (hand application to crop < 50 cm)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub> 520000	NOEC 12000	EC <sub>50</sub> 690000	NOEC 15000	E <sub>r</sub> C <sub>50</sub> 200000	E <sub>b</sub> C <sub>50</sub> 31100
AF		100	10	100	10	10	10
RAC (µg/L)		5200	1200	6900	1500	20000	3110
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)						
<b>Step 1</b>							
-	27.01	0.005	0.023	0.004	0.018	0.001	0.009
<b>Step 2</b>							
S-Europe	9.30	0.002	0.008	0.001	0.006	<0.001	0.003
N-Europe	11.55	0.002	0.010	0.002	0.008	0.001	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-9:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in spring cereals

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
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Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>
AF		400	10	400	10	10	10
RAC (µg/L)		52000	1200	69000	1500	200000	31100
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)						
Step 1							
	27.04	0.005	0.023	0.004	0.018	0.001	0.009
Step 2							
S-Europe	0.30	0.002	0.008	0.001	0.006	<0.001	0.003
N-Europe	1.82	0.001	0.004	0.001	0.003	<0.001	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in winter oilseed rape

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>
AF		400	10	400	10	10	10



AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[illegible]

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
	27.01	0.005	0.023	0.004	0.018	0.001	0.009
Step 2							
S-Europe	0.30	0.002	0.008	0.001	0.006	<0.001	0.003
N-Europe	1.82	0.001	0.004	0.001	0.003	<0.001	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in sunflower

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub> 520000	NOEC 12000	EC <sub>50</sub> 600000	NOEC 15000	EC <sub>50</sub> 200000	EC <sub>50</sub> 31100
AF		100	10	100	10	10	10
RAC (µg/L)		5200	1200	6000	1500	20000	3110
FOCUS Scenario	PEC <sub>calc</sub> max (µg/L)						
Step 1							
	27.01	0.005	0.023	0.004	0.018	0.001	0.009
Step 2							
S-Europe	0.30	0.002	0.008	0.001	0.006	<0.001	0.003
N-Europe	1.82	0.001	0.004	0.001	0.003	<0.001	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in maize

Group		Fish-acute	Fish-prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Myriophyllum aquaticum</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>
AF		400	10	400	10	40	10
RAC (µg/L)		5200	1200	6900	1500	20000	3110
FOCUS Scenario	PEC <sub>gl</sub> max (µg/L)						
Step 1							
	27.04	0.005	0.023	0.004	0.018	0.001	0.009
Step 2							
S-Europe	9.30	0.002	0.008	0.001	0.006	<0.001	0.003
N-Europe	4.82	0.001	0.004	0.001	0.003	<0.001	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in pome fruits and grapevine (hand application to crop < 50 cm)

Group		Fish-acute	Fish-prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Myriophyllum aquaticum</i>
Endpoint		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
(µg/L)		520000	12000	690000	15000	200000	81400
AF		100	10	100	10	10	10
RAC (µg/L)		5200	1200	6900	1500	20000	8140
FOCUS Scenario	PEC <sub>gl</sub> max (µg/L)						
Step-1							
	27.04	0.005	0.023	0.004	0.018	0.001	0.009
Step-2							
S-Europe	9.30	0.002	0.008	0.001	0.006	<0.001	0.003
N-Europe	4.82	0.001	0.004	0.001	0.003	<0.001	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

**Table 9.5-4:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Step 1 and 2 calculations for the use of CANDELA in winter cereals, spring cereals, winter and spring oilseed rape, sunflower, maize, pome fruits and grapevine (hand application to crop < 50 cm)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Test species		-	-	<i>Daphnia magna</i>	-	<i>Desmodesmus subspicatus</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	E <sub>r</sub> C <sub>50</sub>	EC <sub>50</sub>
AF		100	10	100	10	10	10
RAC (µg/L)		-	-	1000	-	11500	12300
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)						
<b>Step 1</b>							
-	42.85	-	-	0.043	-	0.004	0.003
<b>Step 2</b>							
S-Europe	45.72	-	-	0.016	-	0.001	0.001
N-Europe	10.36	-	-	0.019	-	0.002	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-15:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in spring cereals

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Test species		-	-	<i>Daphnia magna</i>	-	<i>Desmodesmus subspicatus</i>	<i>Lemna gibba</i>
Endpoint		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	E <sub>r</sub> C <sub>50</sub>	EC <sub>50</sub>

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
(µg/L)		1	1	≤1000000	1	≤115000	≤123000
AF		100	10	100	10	10	10
RAC (µg/L)		1	1	1000	1	11500	12300
FOCUS Scenario	PEC <sub>GL</sub> mus (µg/L)						
Step-1							
	42.85	1	1	0.043	1	0.004	0.003
Step-2							
S-Europe	15.72	1	1	0.016	1	0.001	0.001
N-Europe	8.43	1	1	0.008	1	0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in winter oilseed rape

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Pest species		1	1	<i>Daphnia magna</i>	1	<i>Desmodesmus subspicatus</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>
AF		100	10	100	10	10	10
RAC (µg/L)		1	1	1000	1	11500	12300

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Inverteb.-prolonged	Algae	Aquatic plants
FOCUS Scenario	PEC <sub>est</sub> max (µg/L)						
Step 1							
	42.85			0.043		0.004	0.003
Step 2							
S-Europe	45.72			0.016		0.001	0.001
N-Europe	49.36			0.019		0.002	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in spring oilseed rape

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Inverteb.-prolonged	Algae	Aquatic plants
Test species				<i>Daphnia magna</i>		<i>Desmodesmus subspicatus</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>
				>100000		>115000	>123000
AF		100	10	100	10	10	10
RAC (µg/L)				1000		11500	12300
FOCUS Scenario	PEC <sub>est</sub> max (µg/L)						
Step 1							
	42.85			0.043		0.004	0.003
Step 2							

Group		Fish-acute	Fish-prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
S-Europe	15.72	1	1	0.016	1	0.001	0.001
N-Europe	8.43	1	1	0.008	1	0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in sunflower

Group		Fish-acute	Fish-prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants
Test species		1	1	<i>Daphnia magna</i>	1	<i>Desmodesmus subspicatus</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	E <sub>50</sub> C <sub>50</sub>	E <sub>50</sub> C <sub>50</sub>
		1	1	>100000	1	>115000	>123000
AF		100	10	100	10	10	10
RAC (µg/L)		1	1	1000	1	11500	12300
FOCUS Scenario	PEC <sub>gt</sub> ms (µg/L)						

Step 1

1	12.85	1	1	0.043	1	0.004	0.003
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Step 2	1	1	1	1	1	1	1
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S-Europe	15.72	1	1	0.016	1	0.001	0.001
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N-Europe	8.43	1	1	0.008	1	0.001	0.001
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AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold



**Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in maize**

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Test species		<i>Pimephales</i>	<i>Pimephales</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Desmodesmus subspicatus</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>
AF		100	10	100	10	10	10
RAC (µg/L)		1	1	1000	1	11500	12300
FOCUS Scenario	PEC <sub>max</sub> (µg/L)						
<b>Step 1</b>							
	42.85	1	1	0.043	1	0.004	0.003
<b>Step 2</b>							
S-Europe	45.72	1	1	0.016	1	0.004	0.004
N-Europe	8.43	1	1	0.008	1	0.004	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CANDELA in pome fruits and grapevine (hand application to crop < 50 cm)**

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
Test species		<i>Pimephales</i>	<i>Pimephales</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Desmodesmus subspicatus</i>	<i>Lemna gibba</i>
Endpoint		EC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>

Group		Fish-acute	Fish-prolonged	Inverteb-acute	Inverteb-prolonged	Algae	Aquatic plants
(µg/L)				≤1000000		≤115000	≤123000
AF		100	10	100	10	10	10
RAC (µg/L)				1000		11500	12300
FOCUS Scenario	PEC <sub>gl-mus</sub> (µg/L)						
Step-1							
	42.85			0.043		0.004	0.003
Step-2							
S-Europe	15.72			0.016		0.001	0.001
N-Europe	8.43			0.008		0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

#### **Glyphosate:**

For all the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an NOEC for *Brachydanio rerio* of 1 mg/L in connection with an assessment factor of 10) in all FOCUS Step 1 ~~s-1-2-scenarios~~. Therefore, no further assessment is necessary.

#### **AMPA:**

For all the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an NOEC for *Pimephales promelas* of 12 mg/L in connection with an assessment factor of 10) in all FOCUS Step 1 ~~s-1-2-scenarios~~. Therefore, no further assessment is necessary.

#### **HMPA:**

For all the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrates as characterised by an EC<sub>50</sub> for *Daphnia magna* of >100 mg/L in connection with an assessment factor of 100) in all FOCUS Step 1 ~~s-1-2-scenarios~~. Therefore, no further assessment is necessary.

### **9.5.3 Overall conclusions**

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 ~~s-1-2-scenarios~~ 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.

#### **Review Comments:**

The relevant predicted environmental concentrations in water (PEC<sub>sw</sub>) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). The risk assessment was based on the worst case PEC values and the results of laboratory toxicity testing.

The PEC/RAC results for glyphosate and its relevant metabolites in surface water are significantly below the trigger value of 1, based on Tier 1 data and FOCUS Step 1 calculations.

The separative risk assessment for the CANDELA was not required, as based on results of the formulation studies for the most sensitive species, the active substance is more toxic.

## **9.6 Effects on bees (KCP 10.3.1)**

### **9.6.1 Toxicity data**

Studies on the toxicity to bees have been carried out with Glyphosate. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of CANDELA were not evaluated as part of the EU assessment of Glyphosate.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees**

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Glyphosate	Oral	LD <sub>50</sub> = 100 µg/bee	EFSA Journal 2015;13(11):4302
<i>Apis mellifera</i>	Glyphosate	Contact	LD <sub>50</sub> > 100 µg/bee	EFSA Journal 2015;13(11):4302
<i>Apis mellifera</i>	Representative formulation	Oral	LD <sub>50</sub> > 77 µg/bee	EFSA Journal 2015;13(11):4302
<i>Apis mellifera</i>	Representative formulation	Contact	LD <sub>50</sub> > 100 µg/bee	EFSA Journal 2015;13(11):4302
<i>Apis mellifera</i>	Glyphosate 54% SL	Oral	LD <sub>50</sub> /48h >400 µg fp (>219.2 µg as)/bee	Lemańska N, 2018, report No. B/61/17
<i>Apis mellifera</i>	Glyphosate 54% SL	Contact	LD <sub>50</sub> /48h >400 µg fp (>219.2 µg as)/bee	Lemańska N, 2018, report No. B/62/17
<i>Apis mellifera</i>	Glyphosate tech.	Chronic adult, 10d	LDD <sub>50</sub> 109.64 µg as/bee/d LC <sub>50</sub> 2794.4 mg as/kg food	Mohanraj M, 2020, report No 6733/2019
<i>Apis mellifera</i>	Glyphosate tech.	Larval, repeated exposure 22 d	ED <sub>10</sub> >100 µg as/larva NOED= 13.16 µg as/larva EC <sub>10</sub> >650 mg as/kg food NOEC 85.60 mg as/kg food	Mohanraj M, 2020, report No 6733/2019
<b>Higher-tier studies (tunnel test, field studies)</b>				
A field study (Thompson, 2012) was undertaken to determine the potential for toxicity to developing honey bee larvae and pupae to glyphosate (tested as the IPA salt) when fed directly to honey bee colonies. In this study the overall NOAEL (No Observed Adverse Effect Level) for brood development of honey bee colonies was 301 mg glyphosate a.e./L sucrose solution, the highest dose tested.				

### 9.6.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 9.6.2 Risk assessment

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 (SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “all crops” also covers the risk for bees from all intended uses (see 9.1.2).

### 9.6.2.1 Hazard quotients for bees

**Table 9.6-2: First-tier assessment of the risk for bees due to the use of CANDELA in all crops**

Intended use	All crops		
Active substance/product	Glyphosate/ CANDELA		
Application rate (g/ha)	1 × 1890		
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	100	1890	<18.90
Contact toxicity	>100		<18.90
Active substance/product	Glyphosate 54% SL (CANDELA)		
Application rate (g/ha)	1 × 1890		
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	>219.2	1890	<8.62
Contact toxicity	>219.2		<8.62

Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure. Q<sub>H</sub> values shown in bold breach the relevant trigger.

### 9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

### 9.6.3 Effects on bumble bees

No data available.

### 9.6.4 Effects on solitary bees

No data available.

### 9.6.5 Overall conclusions

First-tier assessments indicate that no unacceptable risk for bees exposed to the product CANDELA is expected according to the proposed intended uses.

#### Review Comments:

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 (SANCO/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.

## 9.7 Effects on arthropods other than bees (KCP 10.3.2)

### 9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Glyphosate. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of CANDELA were not evaluated as part of the EU assessment of Glyphosate.

**Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods**

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i>	MON 52276 (360 g glyphosate/L SL)	Extended laboratory test Leaf discs (2D)	ER <sub>50</sub> ≥ 12 L/ha (4320 g a.s./ha)	EFSA Journal 2015;13(11):4302
<i>Aphidius rhopalosiphi</i>	MON 52276 (360 g glyphosate/L SL)	Extended laboratory test whole plants (3D)	LR <sub>50</sub> > 16 L/ha (5760 g a.s./ha)	EFSA Journal 2015;13(11):4302
<i>Aleochara bilineata</i>	MON 52276 (360 g glyphosate/L SL)	Extended laboratory test soil	ER <sub>50</sub> > 12 L/ha (4320 g a.s./ha)	EFSA Journal 2015;13(11):4302
<i>Typhlodromus pyri</i>	MON 52276 (360 g glyphosate/L SL)	Extended laboratory test leaves, bean plants (2D)	Mortality: LR <sub>50</sub> > 5760 g a.s./ha  Reproduction: 5760 g a.s./ha > ER <sub>50</sub> ≥ 4320 g a.s./ha (reduction in no. of egg/female 45% at 4320 g a.s./ha)	EFSA Journal 2015;13(11):4302
<i>Aphidius rhopalosiphi</i>	MON 52276 (360 g glyphosate/L SL)	Extended laboratory test barley plants (3D)	Mortality: LR <sub>50</sub> > 5760 g a.s./ha  Reproduction (increase in no. of mummies/female): 46.8 % at 5760 g a.s./ha 43.0 % at 4320 g a.s./ha 32.3 % at 2880 g a.s./ha	EFSA Journal 2015;13(11):4302
<i>Aleochara bilineata</i>	MON 52276 (360 g glyphosate/L SL)	Extended laboratory test soil	Mortality: LR <sub>50</sub> > 4320 g a.s./ha  Reproduction: ER <sub>50</sub> > 4320 g a.s./ha (effects between 1.9-18.1% on reproduction)	EFSA Journal 2015;13(11):4302

Species	Substance	Exposure System	Results	Reference
<i>Aphidius rhopalosiphii</i>	Glyphosate 54% SL	Extended laboratory test barley plants (3D)	LR <sub>50</sub> and ER <sub>50</sub> are > 7 L fp (> 3.8 kg as)/ha	Lemańska N, report No B/63/17
<i>Typhlodromus pyri</i>	Glyphosate 54% SL	Extended laboratory test bean leaves (3 2D)	LR <sub>50</sub> and ER <sub>50</sub> are > 7 L fp (> 3.84 kg as)/ha	Lemańska N, report No B/64/17
<i>Poecilius cupreus</i>	Glyphosate 54% SL	Laboratory test quartz sand (2D)	Mortality LR <sub>50</sub> = 7.38 L fp (4044 g as)/ha Food consumption ER <sub>50</sub> = 7.38 L fp (4044 g as)/ha	Angayarkanni V, 2020, report No 6131/2019
<i>Chrysoperla carnea</i>	Glyphosate 54% SL	Extended laboratory test bean leaves (3 2D)	Mortality LR <sub>50</sub> = 11.72 L fp (6410.8 g as)/ha Reproduction ER <sub>50</sub> is 8.47 8.74 L fp (4790 g as)/ha	Mohanraj M, 2019, report No 6132/2019
<b>Field or semi-field tests</b>				
None				

### 9.7.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

#### 9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “all crops” also covers the risk for non-target arthropods from all intended uses (see 9.1.2).

**Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of CANDELA in all crops**

Intended use	All crops		
Active substance/product	Glyphosate / CANDELA		
Application rate (g/ha)	1 x 1890 g a.s./ha		
MAF	1		
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER <sub>in-field</sub> (g/ha)	PER <sub>in-field</sub> below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	>4320	1890	yes
<i>Aphidius rhopalosiphi</i>	>5760		yes
<i>Aleochara bilineata</i>	>4320		yes
Active substance/product	Glyphosate 54% SL (CANDELA)		
Application rate (g/ha)	1 x 1890 g a.s./ha		
MAF	1		
Test species Tier I	LR <sub>50</sub> / ER <sub>50</sub> (lab.) (g as/ha)	PER <sub>in-field</sub> (g as/ha)	HQ <sub>in-field</sub> criterion: HQ ≤ 2
<i>Poecilus cupreus</i>	4044/ 4044	1890	0.47/ 0.47
Test species Tier II	LR <sub>50</sub> / ER <sub>50</sub> (lab.) (g as/ha)	PER <sub>in-field</sub> (g as/ha)	HQ <sub>in-field</sub> criterion: HQ ≤ 1
<i>Typhlodromus pyri</i>	>3800/ >38008 >3804/ >3804	1890	<0.5/ <0.5
<i>Aphidius rhopalosiphi</i>	>3800/ >3800		<0.5/ <0.5
<i>Chrysoperla carnea</i>	6410/ 4790		0.29/ 0.39

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

The PER<sub>in-field</sub> for *T. pyri*, *A. rhopalosiphi* and *A. bilineata* fall below the rate with <50% effects, indicating that CANDELA does not pose an unacceptable risk to non-target arthropods in in-field areas.

### 9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “all crops” also covers the risk for non-target arthropods from all intended uses (see 9.1.2).

**Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of CANDELA in all crops**

<b>Intended use</b>	All crops				
<b>Active substance/product</b>	Glyphosate / CANDELA				
<b>Application rate (g/ha)</b>	1 x 1890 g a.s./ha				
<b>MAF</b>	1				
<b>vdf</b>	10 (Tier 1, 2D studies) / 1 (higher-tier, 3D studies)				
<b>Test species Higher-tier</b>	<b>Rate with ≤ 50 % effect* (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>CF</b>	<b>corr. PER<sub>off-field</sub> below rate with ≤ 50 % effect?</b>



<i>Typhlodromus pyri</i>	>4320	2.77	5.24	5	yes
<i>Aphidius rhopalosiphi</i>	>5760		52.35		yes
<i>Aleochara bilineata</i>	>4320				
<b>Active substance/product</b>		Glyphosate 54% SL (CANDELA)			
<b>Application rate (g/ha)</b>		1 x 1890 g a.s./ha			
<b>MAF</b>		1.0			
<b>Vdf</b>		10 (tier I), 1 (tier II)			
<b>Test species Tier I</b>	<b>LR<sub>50</sub> (lab.) (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>CF</b>	<b>HQ<sub>off-field</sub> criterion: HQ ≤ 2</b>
<i>Poecilus cupreus</i>	4044/ 4044	0.0277	5.24	10	<0.01/ <0.01
<b>Test species Tier II</b>	<b>LR<sub>50</sub> (lab.) (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>CF</b>	<b>HQ<sub>off-field</sub> criterion: HQ ≤ 2</b>
<i>Typhlodromus pyri</i>	<3800/ >38008 >3804/ >3804		5.24		<0.01/ <0.01
<i>Aphidius rhopalosiphi</i>	>3800/ >3800	0.0277	52.4	5	<0.01/ <0.01 <0.07/ <0.07
<i>Chrysoperla carnea</i>	6410/ 4790		5.24		<0.01/ <0.01

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

The corrected PER<sub>off-field</sub> for *T. pyri*, *A. rhopalosiphi* and *A. bilineata* fall below the rate with <50% effects, and calculated HQ values are below the relevant triggers of 2 (tier I studies) and 1 (tier II studies) indicating that CANDELA does not pose an unacceptable risk to non-target arthropods in off-field areas.

### 9.7.2.3 Additional higher-tier risk assessment

Not relevant.

### 9.7.2.4 Risk mitigation measures

No risk mitigation needed.

### 9.7.3 Overall conclusions

The PER<sub>in-field</sub> and corrected PER<sub>off-field</sub> fall below the rate with <50% effects, indicating that CANDELA does not pose an unacceptable risk to non-target arthropods in in-field and off-field areas.

#### Review Comments:

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.

## 9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

### 9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Glyphosate and its relevant metabolite. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of CANDELA were not evaluated as part of the EU assessment of Glyphosate.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)**

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Glyphosate	Mixed into substrate / 14 d, acute 10 % peat content	LC <sub>50</sub> = 5600 mg/kg dw	EFSA Journal 2015;13(11):4302
<i>Eisenia andrei</i>	AMPA	Mixed into substrate 14 d, acute 10 % peat content	LC <sub>50</sub> > 1000 mg/kg dw	EFSA Journal 2015;13(11):4302
<i>Eisenia fetida</i>	MON 52276 (360 g glyphosate/L SL)	Mixed into substrate / 14 d, acute 10 % peat content	LC <sub>50</sub> > 1250 mg/kg dry soil equivalent to LC <sub>50</sub> > 388 mg a.e./kg dry soil	EFSA Journal 2015;13(11):4302
<i>Eisenia fetida</i>	MON 0139 (63.81 % w/w Glyphosate IPA salt)	Mixed into substrate 56 d, chronic 10 % peat content	NOEC > 1000 mg/kg dry soil equivalent to 473 mg glyphosate acid/ kg dry soil	EFSA Journal 2015;13(11):4302
<i>Eisenia fetida</i>	AMPA	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 131.90 mg/kg dry soil	EFSA Journal 2015;13(11):4302
<i>Hypoaspis aculeifer</i>	Glyphosate IPA-salt	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 1000 mg/kg dw equivalent to 472.8 mg glyphosate acid/ kg dw	EFSA Journal 2015;13(11):4302
<i>Hypoaspis aculeifer</i>	AMPA	Mixed into substrate / Overspray 14 d, chronic 5 % peat content	NOEC = 320 mg/kg dry soil	EFSA Journal 2015;13(11):4302
<i>Folsomia candida</i>	Glyphosate IPA-salt	Mixed into substrate 28 d, chronic 10 % peat content	NOEC = 1000 mg/kg dw equivalent to 587 mg glyphosate acid/ kg dw	EFSA Journal 2015;13(11):4302
<i>Folsomia candida</i>	AMPA	Mixed into substrate 28 d, chronic	NOEC = 315 mg/kg dw	EFSA Journal 2015;13(11):4302

Species	Substance	Exposure System	Results	Reference
		5 % peat content		
<i>Eisenia fetida</i>	Glyphosate 54% SL	Mixed into substrate 56 d, chronic 10 % peat content	Reproduction: EC <sub>10</sub> = 70.19 mg fp (31.09 mg as)/kg dw soil NOEC = 95.26 mg fp (42.19 mg as)/kg dw soil Mortality LC <sub>10</sub> > 1000 mg fp (442.90 mg as)/kg dw soil NOEC > 1000 mg fp (442.90 mg as)/kg dw soil	Mohanraj M, 2019, report No 5044/2019
<i>Folsomia candida</i>	Glyphosate 54% SL	Mixed into substrate 28 d, chronic 10 % peat content	Reproduction: EC <sub>10</sub> = 398.21 mg fp (176.37 mg as)/kg dw soil NOEC = 308.64 mg fp (136.70 mg as)/kg dw soil Mortality LC <sub>10</sub> = 167.75 mg fp (74.30 mg as)/kg dw soil NOEC = 171.47 mg fp (75.94 mg as)/kg dw soil	Angayarkanni V, 2019, report No5167/2019
<i>Hypoaspis aculeifer</i>	Glyphosate 54% SL	Mixed into substrate 10 d, chronic 5 % peat content	EC <sub>10</sub> = 297.87 mg fp (131.93 mg as)/kg dw soil NOEC ≥ 1000 mg fp (≥ 442.90 mg as)/kg dw Mortality LC <sub>10</sub> = 70.12 mg fp (31.06 mg as)/kg dw soil NOEC = 171.47 mg fp (75.94 mg as)/kg dw soil	Angayarkanni V, 2019, report No4854/2019
<b>Field studies</b>				
No data, not required				
<b>Litter bag test</b>				
No data, not required				

### 9.8.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

## 9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

### 9.8.2.1 First-tier risk assessment

The relevant  $PEC_{soil}$  for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is to be considered for Glyphosate.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Pome/stone fruits and grape vine also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

**Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use CANDELA in Pome/stone fruits and grape vine**

Intended use	Pome/stone fruits and grape vine		
Acute effects on earthworms			
Product/active substance	LC <sub>50</sub> (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>a</sub> (criterion TER ≥ 10)
Glyphosate	5600	2.895*	1934.37
AMPA	≥1000	2.703*	≥369.96
Chronic effects on earthworms			
Product/active substance	NOEC/EC <sub>10</sub> (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Glyphosate	473	2.895*	163.39
AMPA	131.90	2.703*	48.80
Glyphosate 54% SL	42.19 31.09	2.895*	14.57 10.7
Chronic effects on other soil macro- and mesofauna- <i>Folsomia candida</i>			
Product/active substance	NOEC/EC <sub>10</sub> /LC <sub>10</sub> (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Glyphosate	587	2.895*	202.76
AMPA	315	2.703*	116.54
Glyphosate 54% SL	208.64 74.3	2.895*	106.61 25.7
Chronic effects on other soil macro- and mesofauna- <i>Hypoaspis aculeifer</i>			
Glyphosate	472.8	2.895*	163.32
AMPA	320	2.703*	118.39
Glyphosate 54% SL	≥442.9 31.06	2.895*	≥152.99 10.7

TER values shown in bold fall below the relevant trigger.

\*  $PEC_{soil}$  accumulation

All the ~~TER<sub>a</sub>~~ and TER<sub>lt</sub> values for glyphosate and its metabolite AMPA are higher than the ~~Annex VI~~ trigger value of ~~10 and~~ 5, respectively, indicating a low acute and long-term risks to earthworms and other non-target soil organism. Therefore, CANDELA poses low acute and long-term risks to earthworms and other non-target soil organisms when applied according to the proposed use rates.

### 9.8.2.2 Higher-tier risk assessment

Not relevant.

### 9.8.3 Overall conclusions

All the ~~TER<sub>a</sub>~~ and TER<sub>lt</sub> values for glyphosate and its metabolite AMPA are higher than the ~~Annex VI~~ trigger value of ~~10 and~~ 5, respectively, indicating a low acute and long-term risks to earthworms and other non-target soil organism. Therefore, CANDELA poses low acute and long-term risks to earthworms and other non-target soil organisms when applied according to the proposed use rates.

#### Review Comments:

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.

## 9.9 Effects on soil microbial activity (KCP 10.5)

### 9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Glyphosate and its relevant metabolite. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of CANDELA were not evaluated as part of the EU assessment of Glyphosate.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms**

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Glyphosate	28 d	6 % effect at day 28 when applied at 33.1 mg a.e./kg dry soil (23 kg/ha)	EFSA Journal 2015;13(11):4302

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	AMPA	28/56 d	21% effect at day 28 at 160 mg /kg d.w.soil (120kg /ha)	EFSA Journal 2015;13(11):4302
N-mineralisation	MON 52276 (360 g glyphosate/L SL)	28 d	8% effect at day 28 at 94 mg /kg d.w.soil (60L/ha)	EFSA Journal 2015;13(11):4302
C-mineralisation	Glyphosate	28 d	9.3% effect at day 28 at 6.4 mg /kg d.w.soil (4.8kg /ha)	EFSA Journal 2015;13(11):4302
C-mineralisation	AMPA	28/56 d	18% effect at day 28 at 160 mg /kg d.w.soil (120kg /ha)	EFSA Journal 2015;13(11):4302
C-mineralisation	MON 52276 (360 g glyphosate/L SL)	28 d	15% effect at day 28 at 94 mg /kg d.w.soil (60L/ha)	EFSA Journal 2015;13(11):4302
N-mineralisation	Glyphosate 54% SL	28 d	9.9% effect on day 28 at 143.99 mg fp (63.93 mg glyphosate)/kg dw soil	Dec W, 2019, report No. G/06/18
C-mineralisation	Glyphosate 54% SL	28 d	10.6% effect on day 28 at 143.99 mg fp (63.93 mg glyphosate)/kg dw soil	Dec W, 2019, report No. G/05/18

### 9.9.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 9.9.2 Risk assessment

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

The relevant  $PEC_{soil}$  for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Pome/stone fruits and grape vine also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

**Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of CANDELA in Pome/stone fruits and grape vine**

Intended use	Pome/stone fruits and grape vine		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	Risk acceptable?
Glyphosate	33.1 (at 28 d)	2.895*	yes
AMPA	160 (at 56 d)	2.703*	yes
Glyphosate 54% SL	63.93 (at 28 d)	2.895*	yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	Risk acceptable?
Glyphosate	6.4 (at 28 d)	2.895*	yes
AMPA	160 (at 56 d)	2.703*	yes
Glyphosate 54% SL	63.93 (at 28 d)	2.895*	yes

\* PEC<sub>soil</sub> accumulation

### 9.9.3 Overall conclusions

Risk assessments conducted with relevant PEC<sub>soil</sub> for the active substance Glyphosate and its metabolite AMPA indicate a low risk to soil microorganisms. Therefore, the application of CANDELA indicate a low risk to soil microorganisms when applied according to the proposed use rates.

#### Review Comments:

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<sub>soil</sub> 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.

### 9.10 Effects on non-target terrestrial plants (KCP 10.6)

#### 9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of CANDELA were not evaluated as part of the EU assessment of Glyphosate.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants**

Species	Substance	Exposure System	Results	Reference
<i>Cyperus rotundus</i> <i>Avena sativa</i> , <i>Triticum aestivum</i> , <i>Zea mays</i> <i>Allium cepa</i> <i>Beta vulgaris</i> <i>Lactuca sativa</i> <i>Brassica napus</i> <i>Cucumis sativa</i> <i>Glycine max</i> <i>Abelmoschus esculentus</i> <i>Rheum rhabarbarum</i>	Glyphosate	28 d Seedling emergence	ER <sub>50</sub> > 4480 (seedling emergence, seedling dry weight) (Not valid)	RAR, October 2015
<b><i>Solanum lycopersicum</i></b> <i>Glycine max</i> <i>Lactuca sativa</i> <i>Raphanus sativus</i> <i>Cucumis sativus</i> <i>Brassica oleracea</i> <i>Avena sativa</i> <i>Lolium perenne</i> <i>Zea mays</i> <i>Allium cepa</i>	Glyphosate	21 d Vegetative vigour	ER <sub>50</sub> = 146 (dry weight)	RAR, October 2015
<i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i> <i>Triticum aestivum</i> <i>Cucumis sativus</i> <i>Brassica napus</i> <i>Raphanus sativus</i> <i>Glycine max</i> <i>Helianthus annuus</i> <i>Lycopersicon esulentum</i>	MON 52276 (360 g glyphosate/L SL)	21 d Vegetative vigour	ER <sub>50</sub> = <b>28.4</b> g a.e./ha Valid with uncertainties	Addendum of the RAR, October 2015; EFSA Journal 2015;13(11):4302
<b><i>Soybean (Glycine max)</i></b> <b><i>Corn (Zea mays)</i></b> <b><i>Onion (Allium cepa)</i></b> <b><i>Oats (Avena sativa)</i></b> <b><i>Radish (Raphanus sativus)</i></b> <b><i>Tomato (Solanum lycopersicon)</i></b>	<b>Glyphosate 54% SL</b>	<b>21 d</b> <b>Vegetative vigour</b>	<b>ER<sub>50</sub> = 0.057 L</b> <b>f.p./ha</b> <b>(31.4 g</b> <b>glyphosate/ha)</b> (Oats, shoot length)	<b>KCP 10.6.2-01</b>
<b><i>Soybean (Glycine max)</i></b> <b><i>Corn (Zea mays)</i></b> <b><i>Onion (Allium cepa)</i></b> <b><i>Oats (Avena sativa)</i></b> <b><i>Radish (Raphanus sativus)</i></b> <b><i>Tomato (Solanum lycopersicon)</i></b>	<b>Glyphosate 54% SL</b>	<b>28 d</b> <b>Seedling emergence</b>	<b>ER<sub>50</sub> = 6.37 L f.p./ha</b> <b>(3509.9 g</b> <b>glyphosate/ha)</b> (Soybean, plant number)	<b>KCP 10.6.2-02</b>

In bold, values used in the risk assessment

### 9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.



## 9.10.2 Risk assessment

### 9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

### 9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “all crops” also covers the risk for non-target terrestrial plants from all intended uses (see 9.1.2).

**Table 9.10-2: Assessment of the risk for non-target plants due to the use of CANDELA in all crops**

<b>Intended use</b>		All crops		
<b>Active substance/product</b>		Glyphosate / CANDELA		
<b>Application rate (g/ha)</b>		1 × 1890 g as/ha		
<b>MAF</b>		1		
<b>Test species</b>	<b>ER<sub>50</sub> (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>TER criterion: TER ≥ 5</b>
<i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i> <i>Triticum aestivum</i> <i>Cucumis sativus</i> <i>Brassica napus</i> <i>Raphanus sativus</i> <i>Glycine max</i> <i>Helianthus annuus</i> <i>Lycopersicon esulentum</i>	28.4	0.0277	52.35	0.5
<i>Soybean (Glycine max)</i> <i>Corn (Zea mays)</i> <i>Onion (Allium cepa)</i> <i>Oats (Avena sativa)</i> <i>Radish (Raphanus sativus)</i> <i>Tomato (Solanum lycopersicon)</i>	31.4	0.0277	52.35	0.60

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

TER value is below the relevant trigger of 5 indicating an unacceptable risk to non-target terrestrial plants following application according to the proposed use patterns. Therefore, further refinements were conducted using risk mitigation measures.

### 9.10.2.3 Higher-tier risk assessment

No new higher-tier studies available.

#### 9.10.2.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

**Table 9.10-3: Risk assessment for non-target terrestrial plants due to the use of CANDELA in all crops considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**

<b>Intended use</b>		All crops			
<b>Active substance/product</b>		Glyphosate			
<b>Application rate (g/ha)</b>		1 × 1890			
<b>MAF</b>		1			
<b>Buffer strip (m)</b>	<b>Drift rate (%)</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>PER<sub>off-field</sub> 50 % drift red. (g/ha)</b>	<b>PER<sub>off-field</sub> 75 % drift red. (g/ha)</b>	<b>PER<sub>off-field</sub> 90 % drift red. (g/ha)</b>
1-3	0.0277	52.35	26.18	13.09	5.24
5	0.0057	10.77	5.39	-	-
10	0.0029	5.48	-	-	-
<b>Toxicity value</b>		<b>TER</b>			
ER <sub>50</sub> = 28.4 g/ha 31.4 g/ha		<b>criterion: TER ≥ 5</b>			
1-3		0.60	1.20	2.40	6.00
5		2.91	5.83	11.66	29.15
10		5.73	11.46	22.92	57.29

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

The refined TER value is above the relevant trigger of 5 when using a no-spray buffer zone of 10 m, indicating that of CANDELA poses an acceptable risk considering this risk mitigation measure. It should however be noted that the no-spray buffer zone could be reduced to 5 m when combined with 50% drift-reducing nozzles or any no-spray buffer zone when 90% drift-reducing nozzles are used.

#### 9.10.3 Overall conclusions

The refined TER value is above the relevant trigger of 5 when using a no-spray buffer zone of 10 m, indicating that of CANDELA poses an acceptable risk considering this risk mitigation measure. It should however be noted that the no-spray buffer zone could be reduced to 5 m when combined with 50% drift-reducing nozzles or any no-spray buffer zone when 90% drift-reducing nozzles are used.

#### Implication for labelling:

**SPe 3:** To protect non-target plants respect an unsprayed buffer zone of 10 m to non-agricultural land OR 5m to non-agricultural land with 50% drift reducing nozzles OR 90% drift reducing.

**Review Comments:**

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).

**9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)**

No additional data are available.

**9.12 Monitoring data (KCP 10.8)**

Not relevant.

**9.13 Classification and Labelling**

	<b>CANDELA</b>
Common Name	CANDELA
<b>Classification and proposed labelling</b>	
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Chronic 2 Code(s) for hazard pictogram(s): GHS09 Signal word: No signal word is used. Hazard statement(s): H411: Toxic to aquatic life with long lasting effects Precautionary statement: P391, P501

CANDELA contains  $\geq 25\%$   $[(M \times 10 \times \text{Chronic 1}) + \text{Chronic 2} \geq 25\%]$  of this active substance, therefore hazard statement H411 is proposed.

## 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 10.2.1.-1	Sadanda TS	2019	Acute toxicity study of Glyphosate 54% SL on <i>Oncorhynchus mykiss</i> Report No. BIO-ETX 036 Bioneeds India Private Limited, Bangalore, Karnataka, India GLP Unpublished	N (study performed for the purpose of registration in non-EU countries)	Sharda Cropchem
KCP 10.2.1.-2	Nimal Christudas IVS	2019	Acute Immobilization Study of Glyphosate 54% SL in Daphnia ( <i>Daphnia magna</i> ) Report No. 18-208-G Vanta Bioscience Limited, Gummidipandi, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.2.1.-3	Nimal Christudas IVS	2019	Growth Inhibition Study of Glyphosate 54% SL in Alga ( <i>Pseudokirchneriella subcapitata</i> ) Report No. 18-207-G Vanta Bioscience Limited, Gummidipandi, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.2.1.-4	Nimal Christudas IVS	2019	Growth Inhibition Study of Glyphosate 54% SL in Lemna sp. ( <i>Lemna gibba</i> ) Report No. 18-210-G Vanta Bioscience Limited, Gummidipandi, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.3.1.1.1	Lemańska N	2018	Glyphosate 54% SL Honeybees ( <i>Apis mellifera</i> L.), Acute Oral Toxicity Test Report No. B/61/17	N	Sharda Cropchem

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
			Institute of Industrial Organic Chemistry, Pszczyna, Poland GLP Unpublished		
KCP 10.3.1.1.2	Lemańska N	2018	Glyphosate 54% SL Honeybees ( <i>Apis mellifera</i> L.), Acute Contact Toxicity Test Report No. B/62/17 Institute of Industrial Organic Chemistry, Pszczyna, Poland GLP Unpublished	N	Sharda Cropchem
KCP 10.3.1.2	Mohanraj M	2020	Chronic Oral Toxicity Study of Glyphosate Technical on adult honey bee ( <i>Apis mellifera</i> ) Report No 6733/2019 Bioscience Research Foundation, Kandamangalam, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.3.1.3	Mohanraj M	2020	Effect of Glyphosate Technical on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure Report No 6735/2019 Bioscience Research Foundation, Kandamangalam, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.3.2.1-1	Angayarkanni V	2020	A laboratory test for evaluating the effects of Glyphosate 54% SL on the carabid beetle, <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae) Report no 6131/2019 Bioscience Research Foundation, Kandamangalam, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.3.2.2-1	Lemańska N	2018	An extended laboratory test for evaluating the effects of Glyphosate 54% SL on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani-Perez) Report No. B/63/17 Institute of Industrial Organic Chemistry, Pszczyna, Poland GLP Unpublished	N	Sharda Cropchem

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 10.3.2.2-2	Lemańska N	2018	An extended laboratory test for evaluating the effects of Glyphosate 54% SL on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Report No. B/64/17 Institute of Industrial Organic Chemistry, Pszczyna, Poland GLP Unpublished	N	Sharda Cropchem
KCP 10.3.2.2-3	Mohanraj M	2019	An extended laboratory test for evaluating the effects of Glyphosate 54% SL on larvae of the green lacewing, <i>Chrysoperla carnea</i> (L.) Report no 6132/2019 Bioscience Research Foundation, Kandamangalam, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.4.1.1-1	Mohanraj M	2019	Effect of Glyphosate 54% SL on reproduction of the earthworm ( <i>Eisenia fetida</i> ) in artificial soil Report no 5044/2019 Bioscience Research Foundation, Kandamangalam, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.4.2.1-1	Angayarkanni V	2019	Effect of Glyphosate 54% SL on the reproduction of the collembolans ( <i>Folsomia candida</i> ) in artificial soil Report no 5167/2019 Bioscience Research Foundation, Kandamangalam, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.4.2.1-2	Angayarkanni V	2019	Effect of Glyphosate 54% SL on the reproductive output of the predatory soil mite <i>Hypoaspis</i> ( <i>Geolaelaps</i> ) <i>aculeifer</i> Canestrini (Acari: Laelapidae) in artificial soil Report no 4854/2019 Bioscience Research Foundation, Kandamangalam, Tamil Nadu, India GLP Unpublished	N	Sharda Cropchem
KCP 10.5-1	Dec W	2019	Glyphosate 54% SL. Soil Microorganisms: Nitrogen Transformation Test Report No. G/06/18	N	Sharda Cropchem

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
			Institute of Industrial Organic Chemistry, Pszczyna, Poland GLP Unpublished		
KCP 10.5-2	Dec W	2019	Glyphosate 54% SL. Soil Microorganisms: Carbon Transformation Test Report No. G/05/18 Institute of Industrial Organic Chemistry, Pszczyna, Poland GLP Unpublished	N	Sharda Cropchem
KCP 10.6.2-01	S. Radha	2021	Effect of Glyphosate 54% SL on vegetative vigour of terrestrial plants 9042/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem
KCP 10.6.2-02	S. Radha	2021	Effect of Glyphosate 54% SL on seedling emergence and seedling growth of terrestrial plants 9041/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem

## Appendix 2 Detailed evaluation of the new studies

### Review Comment:

In order to provide sufficient detail, where appropriate, the following study summaries have been adapted by the zRMS from the full study reports provided in the dossier. zRMS text is highlighted in grey. The comments on individual studies are provided in grey comment boxes.

### A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

#### A 2.1.1 KCP 10.1.1 Effects on birds

##### A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

##### A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

#### A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

##### A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

##### A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

#### A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

### A 2.2 KCP 10.2 Effects on aquatic organisms

#### A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Comments of zRMS:	<p>The study was conducted to OECD guideline 203 and according to the principles of GLP.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- Mortality in the control group was 0% at the termination of the test during the limit test (validity criterion: should not exceed 10%);</li> <li>- Dissolved oxygen concentration in test media was above 77.8% of the air saturation value during the limit test (validity criterion: should be at least 60%);</li> <li>- The results of Chemical analyses were found to be within the acceptable range of <math>\pm 20\%</math> to the nominal concentration of</li> </ul>
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	<p>Glyphosate 54% SL.</p> <p>The study is considered to be reliable and suitable for the risk assessment. All results refer to nominal concentrations.</p>
Reference:	KCP 10.2.1.-1
Report	Acute toxicity study of Glyphosate 54% SL on <i>Oncorhynchus mykiss</i> , Sadananda TS, 2019, report No. BIO-ETX 036
Guideline(s):	Yes, OECD guideline No. 203
Deviations:	No-Yes,
GLP:	Yes
Acceptability:	<p>Yes:</p> <p>One deviation has occurred during the conduct of the study, Temperature, pH and dissolved oxygen was recorded at beginning and at 24 hour intervals in spent Solutions until completion of the test during dose range finding study, instead of recording at 24 hour intervals in fresh and spent Solutions. As the dose range finding test conducted under static condition this deviation does not have any impact on the outcome of the study.</p>
Duplication (if vertebrate study)	No (study performed for the purpose of registration in non-EU countries)

The acute toxicity of Glyphosate 54% SL was tested on freshwater fish, Rainbow trout (*Oncorhynchus mykiss*) was conducted as a static test. A group of 7 rainbow trouts of body length of approximately 4.7-5.8 cm were exposed for 96 h to the test item concentration of 250 mg/L, additional 7 untreated fish served as control. The test vessels were glass aquaria with a capacity of 50 L. There was one replicate of each test item concentration and the control. The fish were observed for mortality and intoxication symptoms after 3, 6, 24, 48, 72 and 96 h of exposure. Neither mortality nor symptoms of intoxication were observed in both the control and the test item concentration during exposure.

The concentrations of active substances was were chemically determined using a validated liquid chromatographic method with MS/MS detection. All test item concentrations and the control were chemically determined at exposure initiation at exposure termination. At exposure initiation, the determined concentration of active substance was 99.76% of the nominal concentration. At exposure termination, the determined concentrations of active substance was 96.12% of the nominal concentrations. The results confirm that the test item concentration was prepared correctly and was maintained through the exposure period.

The endpoint values were determined based on the nominal concentrations of test item and active substances

## Material and methods

Test item:	<p>Glyphosate 54% SL</p> <p>batch number: SCL-35984</p> <p>glyphosate (acid) content: 548 g/L</p> <p>manufacture date: March 19, 2018</p> <p>expiry date: March 18, 2020.</p>
Test organism:	<p>Rainbow trout (<i>Oncorhynchus mykiss</i>.)</p> <p>age: not specified</p> <p>average weight: 1.037 g</p> <p>average body length: 4.7- 5.8 cm</p> <p>supplier: Fisheries Research and Information Center, Hebbal, Bangalore, Karnataka, India</p>

**Test design:** Static system, 96 h of exposure  
one replicate of each test item concentration and control  
seven fish in each aquarium,  
the ratio of fish weight per volume (50 L): 0.63 g/L.

**Nominal test item concentrations:** 250 mg fp/L

**Nominal concentrations of glyphosate:** not reported

**Test conditions:** temperature of water: 15.2 – 15.2 °C  
pH: 6.6 – 6.82;  
dissolved oxygen concentration: 77.8 – 85.6%  
total hardness: 248 mg CaCO<sub>3</sub>/L  
lighting daily cycle: not reported

**Chemical determinations:** The concentrations of the active substances were determined with a validated liquid chromatographic method with MS/MS detection.

**Statistics:** Not performed, no mortalities nor behavioural abnormalities were observed.

**Endpoint values:** LC<sub>50</sub>, NOEC.

## Results:

### Table: Summary of analytical method validation

LOQ [mg as/L]	% recovery	Precision (%RSD)	Linearity (r <sup>2</sup> )	Specificity
Not reported				

### Table: Analytical verification of the dicamba glyphosate concentration in water (1<sup>st</sup> renewal)

Nominal test item concentration [mg/L]	Nominal concentration of glyphosate [mg/L]	Average concentration test item measured in samples collected [mg/L]			
		at exposure initiation	% of the nominal concentration	at exposure termination	% of the nominal concentration
250	Not reported	249.4	99.76	240.31	96.12

### Table: Summary of the test endpoints

Endpoint values [mg/L]	Time of exposure			
	24h	48h	72h	96h
Endpoint values based on the nominal concentrations of product				
LC <sub>50</sub>	>250			
NOEC	≥250			

(-) the 95% confidence interval

## Conclusions

The LC<sub>50</sub>/ 96 h of exposure is >250 mg fp/L, corresponding to >135 mg glyphosate/L. The NOEC/96 h value is ≥250 mg fp/L.

Comments of zRMS:	<p>The study was conducted to OECD guideline 202 and according to the principles of GLP. No deviations to the guideline were noted.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- In the control, not more than 10 percent of the Daphnids should have been immobilised (was 0%).</li> <li>- The dissolved oxygen concentration at the end of the test should be ≥ 3 mg/ L in control and test vessels (was 8.55 mg/L).</li> </ul> <p>The study is considered to be reliable and suitable for the risk assessment. All results refer to nominal concentrations.</p>
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**Reference:** KCP 10.2.1.-2

**Report:** Acute Immobilization Study of Glyphosate 54% SL in Daphnia (Daphnia magna), Nimal Christudas IVS, 2019, report No. 18-208-G

**Guideline(s):** Yes, OECD guideline No. 202

**Deviations:** No

GLP: Yes

Acceptability: YES

Duplication (if vertebrate study) No

The acute toxicity of Dicamba Glyphosate 54% SL was tested on aquatic invertebrate, *Daphnia magna*, conducted as a static test. A group of 4 replicates each containing 5 *Daphnia* neonates, <24 h old, were exposed for 48 h to the test item concentration of 100.0 mg/L; additional 4 replicates of 5 *daphnia* served as control. The test vessels were glass beakers with a capacity of 100 mL, containing 50 mL test medium (natural ground water) each. The *daphnia* were observed for immobilisation after 24 and 48 h of exposure.

The concentrations of active substances were chemically determined using a validated liquid chromatographic method. Test item concentrations and the control were chemically determined at exposure initiation at exposure termination.

At exposure initiation, the determined concentration of active substance was 92% of the nominal concentration. At exposure termination, the determined concentration of active substance was 94% of the nominal concentrations. The results confirm that the test item concentration was prepared correctly and was maintained through the exposure period.

Since no immobilisation was observed, statistical evaluation was not required.

The endpoint values were determined based on the nominal test item concentrations and nominal concentrations of active substances.

## Material and methods

Test item: Glyphosate 54% SL  
batch number: SCL-35984  
glyphosate (acid) content: 548 g/L  
manufacture date: March 19, 2018  
expiry date: March 18, 2020.

Test organism: *Daphnia magna*  
age: < 24 h neonates  
source: Bharathiyar University, India

Test design: Static system, 48 h of exposure  
4 replicates/ treatment and control  
5 *daphnia*/ replicate

Nominal test item concentrations: 100 mg fp/L

Nominal concentrations of glyphosate: 44.29 mg as/L

Test conditions: temperature: 20.0 – 20.2°C  
pH: 7.3 – 7.9  
dissolved oxygen concentration: 8.51- 8.55 mg/L  
hardness: 210 mg CaCO<sub>3</sub>/L  
conductivity: 0.3 mS/ cm  
lighting daily cycle: 16 h light: 8 h dark  
no feeding; no aeration.

Chemical determinations: The concentrations of the active substances were determined with a validated liquid chromatographic method

Statistics: Not performed, no mortalities nor behavioural abnormalities were observed.

Endpoint values: LC<sub>50</sub>, LOEC and NOEC.

## Results:

Table: Summary of analytical method validation

LOQ [mg]	%	Precision	Linearity	Specificity
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as/L	recovery	(%RSD)	(r <sup>2</sup> )	
1.0	90	1.29	0.9993	no signal of detected substance was overlapping with the matrix signal of the control samples

**Table: Analytical verification of the glyphosate concentration in water**

Nominal test item concentration [mg/L]	Nominal concentration of glyphosate [mg/L]	Average concentration (n=3) of glyphosate measured in samples collected [mg/L]			
		at exposure initiation	% of the nominal concentration	at exposure termination	% of the nominal concentration
100.0	44.30	40.54	92 +/- 0.71	41.65	92 +/- 1.41

**Table Immobilisation of daphnia**

Nominal test item concentration [mg/L]	Number of Daphnia magna	Number of immobilised Daphnia magna		% immobilised Daphnia magna	
		24h	48h	24h	48h
0	20	0	0	0	0
100	20	0	0	0	0

**Table: Summary of the test endpoints**

Endpoint values [mg/L]	Time of exposure	
	24h	48h
Endpoint values based on the nominal concentrations of Clomazone 48% EC Glyphosate 54% SL		
EC <sub>50</sub>	>100	>100
NOEC	≥100	≥100

## Conclusions

The EC<sub>50</sub>/ 48 h of exposure is >100 mg fp/L, corresponding to >44.29 mg glyphosate/L. The NOEC/96 h value is ≥100 mg fp/L.

Comments of zRMS:	<p>The study was conducted to OECD guideline 201 and according to the principles of GLP. No deviations to the guideline were noted.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- The biomass in the control cultures increased by a factor of 52.29 (which was more than 16 times) within the 72-hours test period;</li> <li>- The mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour test) in the control cultures was 32.79% (must not exceed 35%);</li> <li>- The coefficient of variation of average specific growth rates during the whole test period in the replicate control culture was 1.5% (must not exceed 7%).</li> </ul> <p>The study is considered to be reliable and suitable for the risk assessment. All results refer to nominal concentrations.</p>
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Reference:	KCP 10.2.1.-3
Report	Growth Inhibition Study of Glyphosate 54% SL in Alga ( <i>Pseudokirchneriella subcapitata</i> ), Nimal Christudas IVS, 2019, report No. 18-207-G
Guideline(s):	Yes, OECD guideline No. 201
Deviations:	No
GLP:	Yes
Acceptability:	YES
Duplication	No

(if vertebrate study)

The growth of the green algae *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*) exposed to the test item, Glyphosate 54% SL, was investigated during a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL containing 100 mL of either the test item concentration or the control per replicate. The initial density of the algae was  $1 \times 10^4$  cells per mL. The flimit test item concentration used was 100 mg fp/L plus the control. Six replicates were used for both test item concentration and control.

The number of algal cells was determined in each replicate after 24, 48 and 72 h of exposure. The inhibition of growth rate was 1.8%. The inhibition of yield was 6.82%.

The concentration of active substances was determined using a validated HPLC. Samples of test item concentration and the control collected at exposure initiation and termination were chemically analyzed. The determined concentration of glyphosate at exposure initiation was 95% of the nominal concentration and at exposure termination 93% of the nominal concentration. The results confirm that the test item concentration was prepared correctly and stable under 72-h test conditions.

The endpoint values were determined based on the nominal test item concentrations as well as based on the nominal concentrations of active substances in the test item.

## Material and methods

Test item:	Glyphosate 54% SL batch number: SCL-35984 glyphosate (acid) content: 548 g/L manufacture date: March 19, 2018 expiry date: March 18, 2020.
Test organism:	the unicellular freshwater green algae, <i>Raphidocelis subcapitata</i> (formerly <i>Pseudokirchneriella subcapitata</i> ) supplier: Bharathiyar University, India
Test design:	Static system, 72 h of exposure 6 replicates for each test item and control initial algal cell density: $1 \times 10^4$ cells per mL.
Nominal test item concentrations:	100 mg fp/L
Nominal concentrations of glyphosate:	44.29 mg as/L
Test conditions:	temperature of water: 22.3 – 22.7°C pH: 7.9 – 8.1 lighting daily cycle: constant light, 5201- 5217 Lx constant shaking, 125-127 rpm medium: OECD
Chemical determinations:	The concentrations of glyphosate were determined with a validated liquid chromatographic method
Statistics:	NOEC and LOEC were calculated using Student T - test. The data was accepted for homogeneity of variance and normality for ANOVA. All the statistical analysis was done using NCSS 12.0.4
Endpoint values:	E <sub>r</sub> C <sub>50</sub> , E <sub>y</sub> C <sub>50</sub>

## Results:

**Table: Summary of analytical method validation**

LOQ [µg as/L]	% recovery	Precision (%RSD)	Linearity (r <sup>2</sup> )	Specificity
1	94	2.69	0.9981	no signal of detected substance was overlapping with the matrix signal of the control samples

**Table: Analytical verification of the glyphosate concentration in test medium**

Nominal test item concentration [mg/L]	Nominal concentration of glyphosate [mg/L]	Average concentration of glyphosate measured in samples collected [mg/L]			
		at exposure initiation	% of the nominal concentration	at exposure termination	% of the nominal concentration

100	44.29	41.85 +/- 0.94	95 +/- 2.12	41.19 +/- 1.53	93 +/- 1.41
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**Table. % inhibition of growth rate and yield of algae**

Nominal test item concentration [mg/L]	Inhibition growth rate (hours)			Inhibition yield (hours)		
	24 h	48 h	72 h	24 h	48 h	72 h
Control	Not reported					
100	13.95	2.78	1.8	26.61	7.92	6.82

**Table: Summary of the test endpoints**

Endpoint	72h values [mg/L]
Endpoint values based on the nominal concentrations of product	
E <sub>r</sub> C <sub>50</sub>	>100
E <sub>y</sub> C <sub>50</sub>	>100
Endpoint values based on the nominal concentrations of glyphosate	
E <sub>r</sub> C <sub>50</sub>	>44.29
E <sub>y</sub> C <sub>50</sub>	>44.29

## Conclusions

The concentration causing a 50% inhibition of the growth rate of *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*), i.e. the E<sub>r</sub>C<sub>50</sub>/72 h value is >100 mg fp/L, corresponding to >44.29 mg glyphosate/L.

The concentration causing a 50% inhibition of yield, i.e. the E<sub>y</sub>C<sub>50</sub>/72 h value, is >100 mg fp/L, corresponding to >44.29 mg glyphosate/L.

Comments of zRMS:	<p>The study was conducted to OECD guideline 221 and according to the principles of GLP. No deviations to the guideline were noted.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- The doubling time was calculated based on the average specific growth rate during 7 days exposure of <i>Lemna</i> and the doubling time was 1.98 days which corresponds to seven fold increase in frond number during seven days and an average specific growth rate of 0.275 per day;</li> <li>- Mean frond numbers in the control group 136 after seven days, or around 11 fold increase over the test period. The average growth rate over the seven day test period in the control was 0.35 day<sup>-1</sup></li> </ul> <p>The study is considered to be reliable and suitable for the risk assessment. All results refer to nominal concentrations.</p>
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Reference:	KCP 10.2.1.-4
Report	Growth Inhibition Study of Glyphosate 54% SL in <i>Lemna</i> sp. ( <i>Lemna gibba</i> ), Nimal Christudas IVS, 2019, report No. 18-210-G
Guideline(s):	Yes, OECD guideline No. 221
Deviations:	No
GLP:	Yes
Acceptability:	YES
Duplication (if vertebrate study)	No

The growth of the aquatic plant *Lemna gibba* exposed to the test item, Nimal Christudas IVS, 2019, report No. 18-208-G, was investigated during a 7 days test. The test was performed in 500 mL glass

beakers containing 250 mL of 20X AAP medium. The following test item concentrations were used: 10, 20, 40, 80, 160 mg fp/L plus the control. For exposure, three replicates were used for each test item concentration and control.

The number of fronds in each replicate was determined after 3, 5 and 7 days of exposure and increase of biomass was measured at the end of exposure. The inhibition of growth rate was between 3.26% and 94.81 % for frond number and between 1.19% and 96.19 % for biomass. The inhibition of yield was between 8.36% and 98.65% and 2.56% and 97.54% for frond number and biomass, respectively.

Samples of each of the test item concentrations of 10, 40 and 160 mg/L collected at exposure initiation and at exposure termination were chemically analyzed.

The determined concentration of glyphosate at exposure initiation was in the range of 96- 98 97% of the nominal concentration and at exposure termination was in the range of 96- 97—98% of the nominal concentration. The results confirm that the test item concentration was prepared correctly and that the determined concentrations of active substances were stable under 7 days test conditions.

The endpoint values were determined based on the nominal test item concentrations as well as based on the nominal concentrations of active substances in the test item.

## Material and methods

Test item:	Glyphosate 54% SL batch number: SCL-35984 glyphosate (acid) content: 548 g/L manufacture date: March 19, 2018 expiry date: March 18, 2020.
Test organism:	<i>Lemna gibba</i> supplier: Bharathiar University, India
Test design:	Static system, 7d of exposure three replicates for each test item concentration and control
Nominal test item concentrations:	10, 20, 40, 80, 160 mg fp/L
Nominal concentrations of glyphosate:	4.43, 8.86, 17.72, 35.44, 70.88 mg as/L
Test conditions:	temperature: 23.6—24.8 24.1-24.3 °C pH: 7.5- 7.6 light: constant, 6850.2- 6879.5 Lx medium: 20x AAP
Chemical determinations:	HPLC
Statistics:	probit, one- way ANOVA (NCSS, Number Cruncher Statistical System).
Endpoint values:	E <sub>r</sub> C <sub>10, 20, 50</sub> , E <sub>y</sub> C <sub>10, 20, 50</sub> , NOEC

## Results:

**Table: Summary of analytical method validation**

LOQ [µg as/L]	% recovery	Precision (%RSD)	Linearity (r <sup>2</sup> )	Specificity
1	91 +/- 2.875	1.27	0.9995	no signal of detected substance was overlapping with the matrix signal of the control samples

**Table: Analytical verification of the glyphosate concentration in test medium**

Nominal test item concentration [mg/L]	Nominal concentration of glyphosate [mg/L]	Average concentration glyphosate measured in samples collected [mg/L]			
		at exposure initiation	% of the nominal concentration	at exposure termination	% of the nominal concentration
10	4.43	4.01 +/- 0.03	91 +/- 0.71	3.94 +/- 0.06	90 +/- 0.71
40	17.72	16.22 +/- 0.12	92 +/- 1.52	16.04 +/- 0.13	91 +/- 0.71
60	26.57	23.91 +/- 0.0	90 +/- 0.0	23.91 +/- 0.0	90 +/- 0.0

**Table Frond number and dry weight**

Nominal test item concentration [mg/L]	FronD number			Dry weight [mg]
	Day 3	Day 5	Day 7	Day 7
0	nr*	nr*	136	42
10	nr*	nr*	125	41
20	nr*	nr*	114	30
40	nr*	nr*	84	22
80	nr*	nr*	31	18
160	nr*	nr*	14	18

nr\* not reported

**Table: Inhibition of growth rate and yield, definitive test**

Nominal test item concentration [mg/L]	Section-by-section growth rate			Mean growth rate	Yield				% Inhibition at exposure termination (day 7)			
									Based on frond number		Based on dry weight	
	0 – 3 d	3 – 5 d	5 – 7 d	0 – 7 d	3 d	5 d	7 d	growth rate	yield	growth rate	yield	
0	nr*	nr*	nr*	0.35	nr*	nr*	124					
3.125	nr*	nr*	nr*	0.34	nr*	nr*	113	3.26	8.36	1.19	2.56	
6.25	nr*	nr*	nr*	0.32	nr*	nr*	102	7.22	17.52	35.50	46.41	
12.5	nr*	nr*	nr*	0.28	nr*	nr*	72	19.9	41.78	71.06	79.64	
25.0	nr*	nr*	nr*	0.14	nr*	nr*	19	60.65	84.37	92.17	94.98	
50.0	nr*	nr*	nr*	0.02	nr*	nr*	2	94.81	98.65	96.19	97.54	

nr\* not reported

**Table: Summary of the test endpoints**

Endpoint	7d values [mg/L]	
	Based on the nominal concentrations of product	Endpoint values based on the nominal concentrations of glyphosate
<b>FronD number</b>		
E <sub>r</sub> C <sub>50</sub>	61.86	27.40
E <sub>r</sub> C <sub>20</sub>	32.91	14.58
E <sub>r</sub> C <sub>10</sub>	23.66	10.48
NOEC	20	9
LOEC	40	18
E <sub>y</sub> C <sub>50</sub>	39.05	17.30
E <sub>y</sub> C <sub>20</sub>	20.14	8.92
E <sub>y</sub> C <sub>10</sub>	14.25	6.31
NOEC	<10	<4
LOEC	10	4
<b>Dry weight</b>		
E <sub>r</sub> C <sub>50</sub>	29.53	13.08
E <sub>r</sub> C <sub>20</sub>	16.01	7.09
E <sub>r</sub> C <sub>10</sub>	11.62	5.15
NOEC	10	4
LOEC	20	9
E <sub>y</sub> C <sub>50</sub>	24.80	10.98
E <sub>y</sub> C <sub>20</sub>	13.83	6.13
E <sub>y</sub> C <sub>10</sub>	10.19	4.51
NOEC	10	4
LOEC	20	9

## Conclusions

The endpoint values based on the nominal test item concentrations:

The frond number: the growth rate E<sub>r</sub>C<sub>50</sub>/7 d value is 61.86 mg fp, corresponding to 27.40 mg glyphosate/L and yield E<sub>y</sub>C<sub>50</sub>/7 d value is 39.05 mg/L (17.30 mg glyphosate/L).



The dry weight: the growth rate  $E_r C_{50}/7$  d value is 29.53 mg fp, corresponding to 13.08 glyphosate/L and yield  $E_y C_{50}/7$  d value is 24.80 mg/L (10.98 glyphosate/L).

**A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms**

**A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms**

**A 2.3 KCP 10.3 Effects on arthropods**

**A 2.3.1 KCP 10.3.1 Effects on bees**

**A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees**

**A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees**

Comments of zRMS:	<p>The study was conducted to OECD guideline 213 and according to the principles of GLP. No deviations to the guideline were noted.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- the average mortality for the total number of controls was 0.0% at the end of the experiment (criterion: it must not exceed 10%),</li> <li>- the <math>LD_{50}/24h</math> of the reference item (dimethoate) was 0.10 µg a.i./bee (criterion: 0.10 - 0.35 µg a.i./bee)</li> </ul> <p>The study is considered to be reliable and suitable for the risk assessment.</p>
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**Reference:** KCP 10.3.1.1.1

**Report** Glyphosate 54% SL Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test, Lemańska N, 2018, report No. B/61/17

**Guideline(s):** Yes, OECD guideline No. 213

**Deviations:** No

**GLP:** Yes

**Acceptability:** YES

**Duplication (if vertebrate study)** No

The acute oral toxicity study of Glyphosate 54% SL was conducted to determine the  $LD_{50}$  values for honeybees. Groups of 30 bees (3 cages as replicates, containing 10 bees each) were exposed to 25, 50, 100, 200 and 400 µg fp (13.7, 27.4, 54.8, 109.6 and 219.2 µg as)/honeybee, each bee was offered 100 µL of a 50% sucrose solution, containing the test item.

The general condition of the test honeybees and the reliability of the tests conducted on them were controlled using the recommended reference item - dimethoate.

After the administration, the insects were observed for mortality and other signs of toxicity 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

## Material and methods

**Test item:** Glyphosate 54% SL  
batch number: SCL-35984  
glyphosate (acid) content: 548 g/L  
manufacture date: March 19, 2018  
expiry date: March 18, 2020.

**Biological test system:** the honeybee, *Apis mellifera* L. strain: carnica  
source: Institute of Industrial Organic Chemistry (IPO), Poland  
age: adults

**Test design:** - test item:  
exposure time: 48 hours  
number of doses: 5 doses and a control  
number of replicates: 3 replicates  
number of bees: 10 bees/replicate  
- reference item:  
exposure time: 24 hours  
number of doses: 3 doses  
number of replicates: 3 replicates  
number of bees: 10 bees/replicate

**Test item doses:** 25, 50, 100, 200 and 400 µg fp /bee  
13.7, 27.4, 54.8, 109.6 and 219.2 µg as/bee

**Reference item doses:** 0.03, 0.06, and 0.12 µg dimethoate/bee

**Test conditions:** temperature: 25 – 27°C  
relative air humidity: 55 - 56%  
place: a dark room

**Endpoints:** - honeybee mortality after 48 hours of exposure (LD<sub>50</sub>)

**Statistical method:** log-probit method using ToxRat Professional software, Version 3.2.1

## Results:

**Table: Summary of the bees mortality and test endpoints**

Dose		Number of tested bees	Mortality after 48 h		LD <sub>50</sub> after 48h	
[µg/bee]	[µg tot as/bee] <sup>b</sup>		[No.]	[%]	[µg/bee]	[µg as/bee] <sup>b</sup>
control	-	30	0	0	-	-
25	13.7	30	0	0	>400	>219.2
50	27.3	30	0	0		
100	54.8	30	0	0		
200	109.6	30	0-1	0-3.3		
400	219.2	30	0	0		

<sup>a</sup>: µg test item/bee

<sup>b</sup>: µg total active substances/bee; 100 µg tot as/bee corresponds to 9.9 µg dicamba + 90.1 µg MCPA/bee

## Conclusions

The median lethal doses (LD<sub>50</sub>/24h and LD<sub>50</sub>/48h) are higher than the maximum used dose, i.e. 400 µg test item/honeybee (>219.2 µg as/honeybee).

### A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	<p>The study was conducted to OECD guideline 214 and according to the principles of GLP. No deviations to the guideline were noted.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- the average mortality for the total number of controls was 0.0% at the end of the experiment (criterion: it must not exceed 10%),</li> <li>- the LD<sub>50</sub>/24h of the reference item (dimethoate) was 0.24 µg</li> </ul>
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	a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee) The study is considered to be reliable and suitable for the risk assessment.
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Reference: KCP 10.3.1.1.2

Report: Glyphosate 54% SL Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test, Lemańska N, 2018, report No. B/62/17

Guideline(s): Yes, OECD guideline No. 214

Deviations: No

GLP: Yes

Acceptability: YES

Duplication (if vertebrate study) No

The acute contact toxicity study of Glyphosate 54% SL was conducted to determine the LD<sub>50</sub> values for honeybees. Groups of 30 bees (3 cages as replicates, containing 10 bees each) were exposed to 25, 50, 100, 200 and 400 µg fp (13.7, 27.4, 54.8, 109.6 and 219.2 µg as)/honeybee, each bee was treated with a volume of 1 µL of the test or reference item solution.

The general condition of the test honeybees and the reliability of the tests conducted on them were controlled using the recommended reference item - dimethoate.

After the administration, the insects were observed for mortality and other signs of toxicity 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

## Material and methods

Test item: Glyphosate 54% SL  
batch number: SCL-35984  
glyphosate (acid) content: 548 g/L  
manufacture date: March 19, 2018  
expiry date: March 18, 2020.

Biological test system: the honeybee, *Apis mellifera* L. strain: carnica  
source: Institute of Industrial Organic Chemistry (IPO), Poland  
age: adults

Test design: - test item:  
exposure time: 48 hours  
number of doses: 5 doses and a control  
number of replicates: 3 replicates  
number of bees: 10 bees/replicate  
- reference item:  
exposure time: 24 hours  
number of doses: 3 doses  
number of replicates: 3 replicates  
number of bees: 10 bees/replicate

Test item doses: 25, 50, 100, 200 and 400 µg fp /bee  
13.7, 27.4, 54.8, 109.6 and 219.2 µg as/bee

Reference item doses: 0.1, 0.2, and 0.4 µg dimethoate/bee

Test conditions: temperature: 25 – 27°C  
relative air humidity: 55 - 56%  
place: a dark room

Endpoints: - honeybee mortality after 48 hours of exposure (LD<sub>50</sub>)

Statistical method: log-probit method using ToxRat Professional software, Version 3.2.1

## Results:

**Table: Summary of the bees mortality and test endpoints**

Dose		Number of tested bees	Mortality after 48 h		LD <sub>50</sub> after 48h	
[µg/bee]	[µg tot as/bee] <sup>b</sup>		[No.]	[%]	[µg/bee]	[µg as/bee] <sup>b</sup>
control	-	30	0	0	-	-
25	13.7	30	0	0	>400	>219.2
50	27.3	30	0	0		
100	54.8	30	0	0		
200	109.6	30	0	0		
400	219.2	30	0	0		

### Conclusions

The median lethal doses (LD<sub>50</sub>/24h and LD<sub>50</sub>/48h) are higher than the maximum used dose, i.e. 400 µg test item/honeybee (>219.2 µg as/honeybee).

### A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 245 and according to the principles of GLP. No deviations to the guideline were noted. The validity criteria of the test were met. The study is considered to be reliable.
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Reference:	KCP 10.3.1.2
Report	Chronic Oral Toxicity Study of Glyphosate Technical on adult honey bee ( <i>Apis mellifera</i> ). Mohanraj M, Study No 6733/2019
Guideline(s):	Yes, OECD guideline No. 245
Deviations:	No
GLP:	Yes
Acceptability:	YES
Duplication (if vertebrate study)	No

### Study on going

The Dose Response Test was conducted based on the results of range finding study and no deviations was observed in Range finding test. The bees were orally treated with control, 45.16, 60.97, 82.30, 111.11 and 150.0 µg/bee concentrations in 50% w/v sucrose solution. Three replications with each replicate consisting of 10 bees were maintained for each concentration. In control group, the bees were treated only with 50% w/v sucrose solution. Feed consumption was recorded for the control and treatment groups for each replicate. After 24 h, the treated diet was withdrawn from the respective treatment group and replaced by freshly prepared treated diet.

At the end of every 24 (10 days exposure) hour observation bees treated with control and treatment group were appeared normal and no toxic sign was observed. At the end of 24 hour observation up to 10 days of exposure, 0% mortality and no clinical signs were observed in bees treated with control and treatment group of 45.16µg/bee concentration. The bees treated with the dose of 60.97 and 82.30 µg/bee concentration, 26.67 and 43.33% were found moribund at the end of the 8<sup>th</sup>, 9<sup>th</sup> and 10<sup>th</sup> day of exposure. The bees treated with the dose of 111.11 µg/bee concentration shows 73.3 % were found moribund from 4<sup>th</sup> day to 10<sup>th</sup> day of exposure. The bees treated with the dose of 150 µg/bee concentration shows 100% were found moribund at the end of the 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> day of exposure. On the completion of the study, all live bees were euthanized with CO<sub>2</sub> exposure and safely disposed.

The reference standard study with dimethoate was also conducted along with dose response test.

The bees were orally treated with 0.8 µg a.i./bees in sucrose solution (50% w/v). In control group, the

bees were treated only with 50% w/v sucrose solution. Feed consumption was recorded for the control and treatment groups for each replicate. After 24 h, the treated diet was withdrawn from the respective treatment group and replaced with freshly prepared treated diet.

After every 24h observation, the feed consumption was recorded and the mean feed consumption are mentioned in the table below:

The bees treated with 0.8 mg/kg ai/bee exhibited mortality and abnormal behaviours during exposure period and at the end of every 24 hour observation was recorded. From day 4 to day 6 the following mortality of 20.0, 36.7 and 33.3 % respectively. Mortality were observed in bees treated with 0.8 mg/kg a.i./bee.

At the end of study period (10 days) the cumulative mortality obtained was 90% in 0.8 mg/kg a.i./bee concentration respectively. On completion of the study all live bees were euthanized with CO2 exposure and safely disposed.

### Dose Response - Mortality

Initial		Consumed		No.	Mortality		LCso	LDD50
Concentration I mg/kg of food]	Dose	Concentration   mg/kg of food]	Dose		total			
					No	[%]		
Glyphosate Technical								
0.0 Control				30	0	0	2794.4 ± 126.22	109.64 ±4.32
0.0 Control with acetone				30	0	0		
1505.3	68.3	1505.3	61.0	30	0	0		
2032.2	75.13	2032.2	82.3	30	8	26.67		
2743.5	82.64	2743.5	113.2	30	13	43.33		
3703.7	90.91	3703.7	143.3	30	22	73.33		
5000	100	5000	161.8	30	30	100.0 0		
Dimethoate								
0.8	0.016	0.8	0.009 30	27 90 Not determined				
Glyphosate Technical	NOEC [mg/kg]				1505.3			
	NOEDD [µg//bee/ day]				61.0			

### Summary of feed consumption data - Dose Response Test

Initial		Consumed		Consumption Of A 50% Sucrose Solution* [mg/bee/day]			Average
Concentration [mg/kg of food]	[µg/bee/	Concentration [mg/kg of food]	Dose	replicates			consumption
				I	II	III	
Glyphosate Technical							
0.0 Control				29.53	29.46	29.09	29.36
0.0 Control with acetone				28.63	28.65	28.56	28.61
1505.3	45.16	1505.3	61.0	27.98	27.84	25.22	27.01
2032.2	60.97	2032.2	82.3	27.09	26.92	27.00	27.00
2743.5	82.30	2743.5	113.2	30.08	26.32	26.12	27.51
3703.7	111.11	3703.7	143.3	25.87	25.92	25.57	25.79
5000	150	5000	161.8	20.32	21.86	22.54	21.57

0.8 (Reference)	0.016	0.8	0.009	17.07	7.47	7.39	10.64	
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## CONCLUSION

Based on the Experimental results, the LDD50 of Glyphosate Technical was determined as  $109.64 \pm 4.32$  (ig as/bee concentration and LC50 was determined  $2794.4 \pm 126.22$  mg/kg. The NOEC was determined as 1505.3 mg/kg and NOEDD was determined as 61.0 (ig as/bee. Reference substance study: The mortality of reference substance 0.8 mg a.i/kg was found to be 90.0% between the stipulated range of 0.5 - 1.0 mg a.i./kg for 10 days exposure on *Apis mellifera*.

## VALIDITY OF THE TEST

- There was no mortality in control and vehicle control group.
- The mortality of reference substance 0.8 mg a.i/kg was found to be 90% between the stipulated range of 0.5 - 1.0 mg a.i./kg for 10 days exposure.

## RESULTS OF ANALYTICAL DOSE VERIFICATION

The determined concentrations of Glyphosate Technical collected at each exposure (Day 1 - 10) were (between 98.7 and 101.7 %) of the nominal concentration. The determined concentrations of Dimethoate (Reference standard) collected at each exposure (Day 1 - 10) were (between 99.2 and 100.6 %) of the nominal concentration. The results confirmed that test item concentration were prepared correctly.

### A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	The study was conducted to OECD guideline 239 and according to the principles of GLP. No deviations to the guideline were noted. The validity criteria of the test were met. The study is considered to be reliable.
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Reference: KCP 10.3.1.3

Report: Effect of Glyphosate Technical on larvae of honey bee, *Apis mellifera* (L.) following repeated exposure. Mohanraj M, Study No 6735/2019

Guideline(s): Yes, OECD guideline No. 239

Deviations: No

GLP: Yes

Acceptability: YES

Duplication (if vertebrate study): No

## Study on-going

The test was carried under laboratory conditions, honey bee larvae (*Apis mellifera* L.) by repeatedly exposed (22 days) to Glyphosate Technical. The toxicity of the Glyphosate Technical was determined at doses of 13.16, 19.75, 29.63, 44.44, 66.66 and 100 µg a.i./larva. The concentrations of test item in the diet was 85.60, 128.40, 192.59, 288.89, 433.33 and 650 mg a.i./kg food. Additionally, honeybee larvae were treated with Dimethoate technical as reference item at a dose of 7.6 µg dimethoate/larva or test concentration 48 mg/kg of diet and with an untreated diet as control.

One day old honey bee larvae (D1) of *Apis mellifera* L (first instar). were transferred from brood combs to polystyrene grafting cells in 48-well cell culture plates before start of the treatment (3 days). On 4 successive days (D3 to D6) the larvae were repeatedly exposed to Glyphosate Technical diluted in the larval food (aqueous sugar solution mixed with royal jelly). After the applications no additional feedings provided to the larvae.

The test carried out with, 8 treatment groups were as: 6 dose of the test item, 2 untreated control groups and 1 dose

of the reference item with 3 replicates per dose and 12 larvae per replicate.

Assessments of cumulated larval mortality were done on days (D4, D5, D6, D7 and D8). Additionally, other observations were reported on D8 such as small body size or large quantities of remaining food. Pupal mortality was assessed at D15 and emergence of adults was evaluated at D22 respectively.

In an analytical phase of the study the concentration of the active substance in the test item solution and in the control was determined.

#### Toxicity of Glyphosate Technical to larvae of *Apis mellifera* L.

Treatment group	Test solution (ID)	Dose [µg a.i./ larva]	Conc. [mg a.i./ kg food]	On D8			On D15		On D22		
				Larval mortality D3 to D8		Mean OO	Pupae stage D8 to D15		Total mortality D3-D22		Adult emergence rate %
				mor. (%>)	corr. (%)	(%)	mor. (%>)	corr. (%)	mor. (%>)	corr. (%)	(%)
<b>Control</b>	A1	-	-	0	-	0	2.78	-	8.33	-	91.67
<b>Vehicle control</b>	A2	-	-	2.78	-	0	5.56	-	11.11	-	88.89
<b>Test Item</b>	T1	13.16	85.60	5.56	2.86	0	11.11	5.88	16.67	6.25	83.33
	T2	19.75	128.40	8.33	5.71	0	11.11	5.88	16.67	6.25	83.33
	T3	29.63	192.59	11.11	8.57	0	13.89	8.82	22.22	12.50	77.78
	T4	44.44	288.89	19.44	17.14	0	22.22	17.65	30.56	21.88	69.44
	T5	66.66	433.33	30.56	28.57	0	38.89	35.29	47.22	40.63	52.78
	T6	100	650	69.44	68.57	0	80.56	79.41	88.89	86.67	11.11
<b>Ref. Item</b>	R1	7.6	48	72.22	72.22	0	86.11	85.71	91.67	90.91	8.33

\*Note: D-Day, Mor- Mortality, corr.-Corrected Mortality, OO-Other observation

Results are averages based on 3 replicates, containing 12 larvae each; see Table 2 for details

corr.: corrected mortality (according to SCHNEIDER-ORELLI1947); reference item was corrected by A1 and test item was corrected by A2;

negative values are set to "0"; calculations are performed with non-rounded values; CL...confidence limit

\*Statistically significant difference in pairwise comparison between treatment and untreated control OO: Other observations (e.g. remaining food)

1 Average% of pupal mortality was calculated according to the following formula:

Sum of dead between D8 and D22 / Sum of living larvae on D8 x 100%

2 Adult emergence [%] = 100 [%] - Mortality of D22 [%]

Treatment	Endpoint: Successful adult emergence	Up to D22
Test item doses	ED <sub>10</sub> [µg a.i./larva] (95% CL)	>100
	ED <sub>20</sub> [µg a.i./larva] (95% CL)	>100
	ED <sub>50</sub> [µg a.i./larva] (95% CL)	54.56±3.51
	NOED [µg a.i./larva]	13.16
Test item concentrations	EC <sub>10</sub> [mg a.i./kg food] (95% CL)	>650
	EC <sub>20</sub> [µg a.i./larva] (95% CL)	>650
	EC <sub>50</sub> [mg a.i./kg food] (95% CL)	354.64±22.82
	NOEC [mg a.i./kg food]	85.60

### Conclusion

In a repeated exposure larval toxicity study with Glyphosate Technical, the ED<sub>50</sub> (successful adult emergence up to D22) was calculated to be 54.56±3.51 µg a.i./larva, which is equivalent to an EC<sub>50</sub> of 354.64±22.82 mg a.i./kg food.

The ED<sub>10</sub> (successful adult emergence up to D22) was calculated to be >100 µg a.i./larva, which is equivalent to an EC<sub>10</sub> of >650 mg a.i./kg food.

The ED<sub>20</sub> (successful adult emergence up to D22) was calculated to be > 100 µg a.i./larva, which is equivalent to an EC<sub>10</sub> of >650 mg a.i./kg food

The NOED was 13.16 µg a.i./larva and the corresponding NOEC was 85.60 mg a.i./kg food.

### Validity of the study

Larval mortality in the Controls:

In control (A1) and vehicle control (A2), the cumulative larval mortality from D3 to D8 was 0% and 2.78% respectively. (Criterion : should be < 15% across all control replicates).

Adult emergence rate :

In control (A1) and vehicle control (A2), the adult emergence rate on D22 was 91.67 % and 88.89% respectively. (Criterion : should be > 70% across all control replicates)

Reference item :

The larval mortality in standard reference Chemical (Dimethoate) on D8 was 72.22% (Criterion : should be > 50% across all reference replicates).

**A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects**

**A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests**

**A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees**

**A 2.3.2 KCP 10.3.2 Effects on non-target arthropods other than bees**

**A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods**

Comments of zRMS:	<p>The study follows the appropriate guidelines and according to the principles of GLP. The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- the mortality of control was 3.33% after 2 weeks (criterion: it must not exceed 6.7%),</li> <li>- the mortality of reference item group was 100% (criterion: 65 ± 35% after 2 weeks)</li> </ul> <p>The study is considered to be valid and suitable for the risk assessment.</p>
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Reference:

10.3.2.1-1

Report

A laboratory test for evaluating the effects of Glyphosate 54% SL on the carabid beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae), Angayarkanni V, 2020, report



no 6131/2019

**Guideline(s):** ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Heimbach U et al, 2000)

**Deviations:** No

**GLP:** Yes

**Acceptability:** Yes

**Duplication  
(if vertebrate study)** No

## Summary

The aim of the ~~extended~~ laboratory test was to evaluating the effects of Glyphosate 54% SL on mortality and food consumption of the of the carabid beetle, *Poecilus cupreus* L. Adult (2-10 wks from hatching) carabid beetles *P. cupreus* were exposed to 5 doses of the test item, 0.875, 1.75, 3.5, 7.0 and 14.0 ml fp/ha, corresponding to 480, 959, 1918, 3836 and 7672 g glyphosate/ha, applied to quartz sand. The duration of the study was 14 days. Beetles were offered fly *Dalia antique* pupae on days 0, 2, 4, 7 and 10. Mortality of the beetles was assessed on 2 hours and 1, 2, 4, 7, 10 and 14 days of exposure and food uptake was assessed on 2, 4, 7, 10 and 14 days of exposure

The mortality LR<sub>50</sub> and the food consumption ER<sub>50</sub> is 7.38 L product (4044 g glyphosate)/ha is 7.38 L product (4044 g glyphosate)/ha.

## Materials and methods

**Test item:** Glyphosate 54% SL  
batch number: SCL-35984  
glyphosate (acid) content: 548 g/L  
manufacture date: March 19, 2018  
expiry date: March 18, 2020

**Test system:** carabid beetle, *Poecilus cupreus* L.,  
adult, 2- 10 wks from hatching

**Source:** BRF Insectary

**Experimental design:** control, 5 treatments, reference item  
5 replicates/ treatment  
6 beetles (3 female & 3 male)/ replicate

**Test substrate:** quartz sand, moisture content 70% WHC

**Test item doses:** control, 0.875, 1.75, 3.5, 7.0 and 14.0 ml fp/ha

**Reference dose:** Parathion, 50% w/w, 9 mL (4.5 g as)/ha

**Test condition:** temperature: 19.8 - 20.2°C  
relative humidity: 68.0 – 75.0%  
light and photoperiod: 16 h light: 8 h dark  
light intensity: 885 - 1275 Lx

**Test duration:** 14 days

**Statistical analysis:** probit and ANOVA (NCSS)

## Results

	Mortality			Food consumption		
	%	%corrected	LR <sub>50</sub> mortality	No of flies consumed/ beetle	% reduction	ER <sub>50</sub> food consumption
control	3.33	-	7.38 L	1.0		7.38 L fp/ha
0.875	6.67	3.45	fp/ha	0.97	3.0	(4044 g as/ha)
1.75	16.66	13.79	(4044 g	0.90	11.0	
3.5	33.33	31.03	as/ha)	0.78	21.0	
7.0	43.33	41.38		0.62	38.0	
14.0	73.33	72.41		0.23	77.0	

NOER	1.75 L fp/ha (959 g as/ha)	1.75 L fp/ha (959 g as/ha)
Parathion, 4.5 g as/ha	100	

### Conclusions

The mortality LR<sub>50</sub> and the food consumption ER<sub>50</sub> is 7.38 L product (4044 g glyphosate)/ha.

## A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing, aged residue with non-target arthropods

Comments of zRMS:	<p>The study follows the appropriate guidelines and according to the principles of GLP. The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>– after 48 hours, mortality of the control group was 0.0% (criterion: a maximum of 10.0%),</li> <li>– after 48 hours, mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 73.3% (criterion: a minimum of 50%),</li> <li>– all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),</li> <li>– the mean number of mummies per female in the control group was 42.9 (criterion: a minimum of 5.0 mummies/female),</li> <li>– all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).</li> </ul> <p>The study is considered to be valid and suitable for the risk assessment.</p>
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Reference:	10.3.2.2-1
Report	An extended laboratory test for evaluating the effects of Glyphosate 54% SL on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (De Stefani-Perez), Lemańska N, 2019, report no B/63/17
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994), ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the Joint Initiative of IOBC, BART, and EPPO (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

### Summary

The aim of the extended laboratory test was to assess the impact of Glyphosate 54% SL on mortality and fecundity of *Aphidius rhopalosiphii*. Adult female wasps were exposed to 3 concentrations of the test item, 1.75, 3.50 and 7.0 L/ha the test item applied to potted barley plants. Mortality was determined 2, 24 and 48 hours after the release of wasps to the test arenas.

For fecundity assessment, females, which survived 48-hour exposure to test the item and the ones from the control group were introduced into fecundity units containing barley plants infested with the aphid, *Rhopalosiphum padi*. After 24 hour oviposition the wasps were removed from the test arenas; the number of mummies (parasitized aphids in which wasps in pupae were developing) was recorded after 12 days. Mortality of the wasps after 48 hours of exposure and the percentage of fecundity reduction 12 days after the oviposition were the endpoints.

The LR<sub>50</sub> and ER<sub>50</sub> were > 7 L fp (> 3.8 kg glyphosate)/ha.

## Materials and methods

Test item:	Glyphosate 54% SL batch number: SCL-35984 glyphosate (acid) content: 548 g/L manufacture date: March 19, 2018 expiry date: March 18, 2020.
Test system:	Species: <i>Aphidius rhopalosiphi</i> (DeStefani-Perez) adult females (24 - 48 hours after emerging from mummies) source: a laboratory-bred culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by Bias Labs (London, UK)
Test design:	Number of treatments: 5 (control, 3 treatments and reference item) Number of replicates 6 Number of wasps per treatment/replicate: 30/5
Plant material:	Barley ( <i>Hordeum vulgare</i> ), BBCH 12
Experimental conditions:	Temperature: 18- 21°C Relative humidity: 62 - 75% Photoperiod: 16 h light: 8 h dark Light intensity: 3260 - 4610 lux
Test duration:	14 days
Endpoints:	- wasp mortality after 48 hours of exposure - reduction in fecundity (Pr) of the surviving female wasps exposed to Glyphosate 54% SL, 12 days after the oviposition period
Statistical analysis:	Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, Chi2 2x2 Table Test with Bonferroni Correction, One-way ANOVA analysis, Dunnett's test

## Results

Application rate (L test item/ha)	Endpoints				
	Mortality after 48 h		Fecundity		
	Total (%)	LR <sub>50</sub>	Mean no. of mummies/female	Fecundity reduction (%)	ER <sub>50</sub>
[L test item/ha] [kg glyphosate/ha]		[L test item/ha] [kg glyphosate/ha]			
Control	0.0	-	42.9	-	-
1.75	0.0	> 7 L/ha	32.9	23.4	> 7 L/ha
3.5	3.3	> 3.8 kg as/ha	36.5	15.1	> 3.8 kg as/ha
7.0	3.3		33.5	22.0	
NOER <sub>mortality</sub>		> 7 L/ha > 3.8 kg as/ha	NOER <sub>reproduction</sub>		> 7 L/ha > 3.8 kg as/ha
Danadim 400 EC	Mortality after 24 h				
5.0 mL (2 g dimethoate)/ha	73.3%				

## Conclusions

The LR<sub>50</sub> and ER<sub>50</sub> are > 7 L fp (> 3.8 kg glyphosate)/ha.

Comments of zRMS:	The study follows the appropriate guidelines and according to the principles of GLP. The validity criteria of the test were met as:
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	<ul style="list-style-type: none"> <li>- mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%),</li> <li>- corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 100.0% on day 7 of exposure (criterion: from 50 to 100%),</li> <li>- the mean number of eggs per female in the control group was 4.5 (required: <math>\geq 4</math> eggs per female).</li> </ul> <p>The study is considered to be valid and suitable for the risk assessment.</p>
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Reference: KCP 10.3.2.2-2

Report: An extended laboratory test for evaluating the effects of Glyphosate 54% SL on the predatory mite, *Typhlodromus pyri* (Sch.), Lemańska N, report No B/64/17

Guideline(s): Yes, ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blumel S et al, 2000)

Deviations: No

GLP: Yes

Acceptability: YES

Duplication (if vertebrate study): No

The extended laboratory test involved the evaluation of the effects of the test item, Glyphosate 54% SL on mortality and fecundity of the predatory mite *Typhlodromus pyri* (Scheuten). Protonymphs, 24 h old, were exposed to 3 concentrations of the test item, 1.75, 3.50 and 7.0 L/ha the test item applied to barley bean leaf discs

Mortality was determined after 7 days of exposure. Observations of reproduction of the control group and all groups treated with the test item were made after 8, 11, and 14 days of the treatment. Mortality of *T.pyri* after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints.

To verify the sensitivity of the mites and the precision of the test procedure, an insecticide, Danadim 400 EC (400 g/L dimethoate), applied at the dose of 9.0 mL/ha (3.6 g dimethoate/ha) was used as a reference item. The control group was treated with distilled water.

The LR<sub>50</sub> and ER<sub>50</sub> were  $> 7$  L fp ( $> 3.8$  kg glyphosate)/ha.

## Materials and methods:

Test item: Glyphosate 54% SL  
batch number: SCL-35984  
glyphosate (acid) content: 548 g/L  
manufacture date: March 19, 2018  
expiry date: March 18, 2020.

Test system: predatory mite, *Typhlodromus pyri* (Scheuten); *Acari, Phytoseidae*  
age: protonymphs (24 hours)  
source: a laboratory-bred culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by Bias Labs (London, UK)

Experimental design: control, 3 doses of test item, reference  
3 replicates/ group, 20 mites/ replicate

Test item doses: 1.75, 3.50 and 7.0 L fp/ha

Reference:	Danadim 400 EC, 9.0 mL/ha (3.6 g dimethoate/ha)
Plant material:	bean, <i>Phaseolus vulgaris</i> L. (Fabaceae) infested with the two-spotted spider mite, <i>Tetranychus urticae</i> Koch
Test conditions:	temperature: 24 –26°C relative air humidity: 63 – 85% photoperiod: 16 hours light (889 lx) 8 hours dark
Statistical analyses:	Probit analysis using max. likelihood regression, Step-down CochranArmitage test procedure, Shapiro Wilk's Test, Levene's Test, Wiliams Multiple Sequential t-test Procedure
Endpoints:	- mite mortality after 7 days of the treatment - LR <sub>50</sub> and NOER <sub>mortality</sub> - reproduction reduction (Pr) after 14 days of the treatment - ER <sub>50</sub> and NOER <sub>reproduction</sub>

## Results:

**Table: The effects of the test item on mortality and fecundity of predatory mites in the extended laboratory test**

Laboratory test		Field test					
Study group [application rate]	Parameter [endpoint]						
Test item [L/ha]	Total [%]	LR <sub>50</sub>		Mean number of eggs/ female (Rr) [no.]	Reproduction reduction Pr [%]	ER <sub>50</sub>	
		Test item [L/ha]	Active ingredient [kg/ha]			Test item [L/ha]	Active ingredient [kg/ha]
Control (0.0)	0	-	-	4.5	-	-	-
1.75	0	>7.0	>3.84	4.2	8.4	>7.0	>3.84
3.5	6.7*			3.4	25.0		
7.0	8.3*			3.9	13.7		
NOER <sub>mortality</sub>		1.75	0.96	NOER <sub>reproduction</sub>		>7.0	>3.84
Reference item [mL/ha]	Danadim 400 EC (dimethoate, 400 g/L)						
9.0	100.0	-	-	-	-	-	-

\*statistically significant difference

## Conclusions

The LR<sub>50</sub> and ER<sub>50</sub> are > 7 L fp (> 3.8 kg glyphosate)/ha.

Comments of zRMS:	<p>The study follows the appropriate guidelines and according to the principles of GLP. The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- mortality in the control was 6.67% (a criterion: ≤ 20%)</li> <li>- fecundity in the control was 38.30 (criterion: ≥ 15)</li> <li>- fertility in the control was 97.63% (criterion: ≥ 70%)</li> <li>- mortality in the reference item was 100% (criterion: ≥ 50%).</li> </ul> <p>The study is considered to be valid and suitable for the risk assessment.</p>
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Reference:	10.3.2.2-3
Report	An extended laboratory test for evaluating the effects of Glyphosate 54% SL on larvae of the green lacewing, <i>Chrysoperla carnea</i> (L), Mohanraj M, 2019, report no 6132/2019
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Candolfi M et al, 2001)

Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

## Summary

The aim of the extended laboratory test was to evaluating the effects of Glyphosate 54% SL on mortality and reproduction of the green lacewing, *Chrysoperla carnea* (L). 2-3 days old larvae were exposed to 5 doses of the test item, 0.875, 1.75, 3.5, 7.0 and 14.0 ml fp/ha, corresponding to 480, 959, 1918, 3836 and 7672 g glyphosate/ha, applied to bean eaves. Larvae were exposed to the test item until at least 5 days after entering the pupae stage, number of pupae and hatching adults were recorded. Mortality of the beetles was assessed on 2 hours and then at least 3 times per week until all the larvae formed pupae. Reproduction was evaluated with 2 synchronisations of eggs laying (24h periods) per week. Fecundity rate was calculated based on the number of eggs per female per day and fertility rate was calculated based on the percent of viable eggs.

The mortality LR<sub>50</sub> is 11.72 L product (6410.8 g glyphosate)/ha and the reproduction ER<sub>50</sub> is 8.47 L product (4790 g glyphosate)/ha.

## Materials and methods

Test item:	Glyphosate 54% SL batch number: SCL-35984 glyphosate (acid) content: 548 g/L manufacture date: March 19, 2018 expiry date: March 18, 2020
Test system:	green lacewing <i>Chrysoperla carnea</i> L. 1 <sup>st</sup> instar larvae, 2- 3 d old
Source:	BRF Insectary
Experimental design:	control, 5 treatments, reference item 30 (mortality) or 10 (reproduction) replicates/ treatment 1 larva (mortality) or 1 female (reproduction)/ replicate
Test substrate:	leaves of potted common beans ( <i>Phaseolus vulgaris</i> L.)
Test item doses:	control, 0.875, 1.75, 3.5, 7.0 and 14.0 ml fp/ha
Reference dose:	Rogohit, 30% dimethoate, 0.65 L (195 g as)/ha
Test condition:	temperature: 24 - 26°C relative humidity: 64.0 – 80.0% light and photoperiod: 16 h light: 8 h dark light intensity: 1200 - 1850 Lx
Test duration:	30 days
Statistical analysis:	probit (NCSS) and one-way ANOVA (GraphPad Prism 8)

## Results

	Mortality			Reproduction				
	%	%corrected	LR <sub>50</sub>	Fecundity		Fertility		ER <sub>50</sub>
				No	% reduction	%	% reduction	
control	6.67		11.72 L	38.30		97.63		8.47 L
0.875	10.0	3.57	fp/ha	35.50	7.31	98.12	-0.5	fp/ha
1.75	16.66	10.71	(6410.8 g	28.90	25.54	97.95	-0.33	(4790 g
3.5	26.67	21.43	as/ha)	26.00	32.11	97.59	0.04	as/ha)
7.0	36.67	32.14		22.20	42.04	97.17	0.47	
14.0	60.00	57.14		15.15	60.44	94.24	3.48	
NOER	7 L fp/ha (3836 g as/ha)			<0.875 L fp/ha (<480 g as/ha)				
Rogohit, 195 g as/ha	-	100	-	-	-	-	-	-

## Conclusions

The mortality LR<sub>50</sub> is 11.72 L product (6410.8 g glyphosate)/ha and the reproduction ER<sub>50</sub> is 8.47 L product (4790 g glyphosate)/ha.

### A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

#### A 2.4.1 KCP 10.4.1 Earthworms

##### A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	<p>The study was conducted to OECD guideline 222 and according to the principles of GLP.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"> <li>- mortality in the control was 0.0% (a criterion: ≤ 10%)</li> <li>- number of juveniles per vessel at the end of the test was 112.38 (criterion: ≥ 30)</li> <li>- coefficient of variation calculated for the number of juveniles was 8.68% (criterion: ≤30%)</li> </ul> <p>The study is considered to be reliable and suitable for the risk assessment.</p>
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Reference: KCP 10.4.1.1-1

Report: Effect of Glyphosate 54% SL on reproduction of the earthworm (*Eisenia fetida*) in artificial soil, Mohanraj M, 2019, report no 5044/2019

Guideline(s): Yes, OECD Guideline No. 222 (2016)

Deviations: None from OECD 222.

GLP: Yes

Acceptability: Yes/No/Supplementary

Duplication (if vertebrate study) No

## Summary

The aim of the study was evaluate effects of Glyphosate 54% SL on reproduction of the earthworm (*Eisenia fetida*) to determine the mortality (LR<sub>50</sub>) and reproduction (EC<sub>10</sub>, NOEC) endpoints. Worms were exposed to 10 concentrations of the test item: 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg test item/kg of dry weight of the artificial soil. Four replicates of 10 worms each were used per concentration; additionally 8 replicates of 10 worms each were used as an untreated control.

Adults were extracted after 28 days of exposure for mortality assessment. The reproduction output, was assessed as number of juvenile worms after next 28 days of exposure.

Samples of each of the test item concentrations of 5.04, 95.26 and 1000 mg/kg collected at exposure initiation, in the middle of the test and at exposure termination were chemically analyzed. The determined concentration of glyphosate across the study were in the range of 97.7- 99.9% of the nominal concentration.

The endpoint values were determined based on the nominal test item concentrations as well as based on the nominal concentrations of active substances in the test item. The EC<sub>10</sub> is 70.19 mg fp (31.09 mg as)/kg dw soil and NOEC is 95.26 mg fp (42.19 mg as)/kg dw soil.

## Material and methods

Test item:	Glyphosate 54% SL batch number: SCL-35984 glyphosate (acid) content: 548 g/L manufacture date: March 19, 2018 expiry date: March 18, 2020
Test organism:	earthworms, <i>Eisenia fetida</i> , 4 months old, individual body weight 342- 440 mg, from a standard laboratory culture at BFR
Test design:	Test duration: 56 days
Artificial soil:	10% peat (a particle size of 2 ± 1 mm), 20% clay, and 70% sand (with more than 50% of the particles between 50 and 200 µm)
Endpoints:	LC <sub>50</sub> , EC <sub>10</sub> , EC <sub>20</sub> , EC <sub>50</sub> , and NOEC
Test conditions:	Temperature: 20.47 - 21.6 °C pH at the beginning of the test: 5.7- 6.08 pH at the end of the test: 5.85 - 6.25 Soil moisture content at the beginning of the test: 50.67- 54.62 mg/kg dw soil Soil moisture content at the end of the test: 53.34- 56.73 mg/kg dw soil 16h light and 8h dark; Light intensity: 562- 568 lux.
Test item concentrations:	control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg f.p./kg dry soil
Chemical analysis:	performed, samples of 5.04, 95.26 and 1000 mg/kg concentrations, sampled on days 0, 28 and 56
Statistical analysis:	probit (NCSS) and ANOVA (GraphPad Prism 8)



## Findings

**Table 8. Number of juvenile earthworms after 8 weeks of the experiment.**

Sample/concentration [mg/kg d.w. soil]	Replicate	Number of juveniles	Mean ± SD	Reduction in comparison to the control [%]	CV* [%]
Control	1	98	112.38 ± 9.75	-	8.68
	2	111			
	3	126			
	4	99			
	5	113			
	6	118			
	7	120			
	8	114			
T1	1	113	111.75 ± 4.72	0.56	4.22
	2	105			
	3	116			
	4	113			
T2	1	108	111.25 ± 5.38	1.00	4.83
	2	118			
	3	113			
	4	106			
T3	1	105	111.50 ± 4.51	0.78	4.04
	2	114			
	3	115			
	4	112			
T4	1	105	110.25 ± 3.86	1.89	3.50
	2	112			
	3	110			
	4	114			
T5	1	110	108.50 ± 8.70	3.45	8.02
	2	120			
	3	104			
	4	100			
T6	1	100	95.50 ± 11.12	15.02	11.64
	2	106			
	3	80			
	4	96			
T7	1	86	75.00 <sup>+</sup> ± 10.39	33.26	13.86
	2	72			
	3	80			
	4	62			
T8	1	68	63.50 <sup>+</sup> ± 10.34	43.49	16.29
	2	60			
	3	75			
	4	51			
T9	1	42	32.75 <sup>+</sup> ± 8.73	70.86	26.66
	2	21			
	3	35			
	4	33			
T10	1	9	10.50 <sup>+</sup> ± 2.65	90.66	25.20
	2	14			
	3	11			
	4	8			

\*CV: coefficient of variation

+ : statistically significant difference between the control and the treatment group at  $p < 0.05$

**Table: Summary of analytical method validation**

LOQ [µg as/L]	% recovery	Precision (%RSD)	Linearity (r <sup>2</sup> )	Specificity
Not reported				

**Table: Analytical verification of the glyphosate concentration in test medium**

Test item concentration (mg/kg)	Nominal concentration of glyphosate (mg as/kg)	Analyzed concentration of glyphosate					
		Day 0		Day 28		Day 56	
		mg as/kg	% nominal	mg as/kg	% nominal	mg as/kg	% nominal
Control	0	-	-	-	-	-	-
5.04	2.24	2.238	99.9	2.22	99.1	2.237	99.9
95.26	42.345	42.223	99.7	42.120	99.5	42.223	97.7
1000.0	444.516	441.764	99.4	441.757	99.4	442.346	99.5

**Table: Summary of the test endpoints**

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]
LC <sub>50</sub>	>1000	>442.90
NOEC	≥1000	≥442.90
EC <sub>10</sub>	70.19	31.09
EC <sub>20</sub>	115.59	51.19
EC <sub>50</sub>	300.19	132.95
NOEC	95.26	42.19
LOEC	171.47	75.94

### Conclusions:

The EC<sub>10</sub> is 70.19 mg fp (31.09 mg as)/kg dw soil and NOEC is 95.26 mg fp (42.19 mg as)/kg dw soil.

#### A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

#### A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

##### A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:	<p>The study was conducted to OECD guideline 232 and according to the principles of GLP.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"><li>- mortality in the control was 0.0% (a criterion: <math>\leq 20\%</math>)</li><li>- number of juveniles per vessel at the end of the test was 778.0 (criterion: <math>\geq 100</math>)</li><li>- coefficient of variation calculated for the number of juveniles was 4.41% (criterion: <math>\leq 30\%</math>)</li></ul> <p>The study is considered to be reliable and suitable for the risk assessment.</p>
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Reference: 10.4.2.1-1

Report: Effect of Glyphosate 54% SL on the reproduction of the collembolans (*Folsomia candida*) in artificial soil, Angayarkanni V, 2019, 5167/2019.

Guideline(s): Yes, OECD No. 232 (2009)

Deviations: No.

GLP: Yes

Acceptability: Yes

Duplication  
(if vertebrate study): No

### Summary

The aim of the study was to evaluate effects of Glyphosate 54% SL on mortality reproduction of the collembolans, *Folsomia candida*.

Springtails were exposed to 10 concentrations of the test item: 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg test item/kg of dry weight of the artificial soil. Four replicates of 10 springtails each were used per concentration; additionally 8 replicates of 10 springtails each were used as an untreated control.

Mortality assessment was performed after 14 days of exposure and the reproduction output was assessed as number of juvenile worms after next 14 days of exposure.

Samples of each of the test item concentrations of 5.04, 95.26 and 1000 mg/kg collected at exposure initiation, in the middle of the test and at exposure termination were chemically analyzed.

The determined concentration of glyphosate across the study were in the range of 97.8- 98.7% of the nominal concentration.

The endpoint values were determined based on the nominal test item concentrations as well as based on the nominal concentrations of active substances in the test item.

The EC<sub>10</sub> is 398.21 mg fp (176.31 mg as)/kg dw soil and NOEC is 308.64 mg fp (136.70 mg as)/kg dw soil.

## Material and methods

Test item:	Glyphosate 54% SL batch number: SCL-35984 glyphosate (acid) content: 548 g/L manufacture date: March 19, 2018 expiry date: March 18, 2020
Test organism:	The collembolan, <i>Folsomia candida</i> , 9-12 days old, obtained from a standard laboratory culture at BFR.
Test design:	Test duration: 28 days
Artificial soil:	5% peat (a particle size of $2 \pm 1$ mm), 20% clay, and 75% sand (with more than 50% of the particles between 50 and 200 $\mu$ m)
Endpoints:	EC <sub>10</sub> , EC <sub>20</sub> , EC <sub>50</sub> , and NOEC
Test conditions:	Temperature: 19.6- 21.4 °C pH at the beginning of the test: 5.62- 5.78 pH at the end of the test: 5.53- 5.86 Soil moisture content at the beginning of the test: 12.92- 13.05% (41.7- 42.5% of the maximum water holding capacity) Soil moisture content at the end of the test: 13.01- 13.10% (42.2- 42.8% of the maximum water holding capacity) Lighting: 16h light and 8h dark; Light intensity: 560- 630 lux.
Test item:concentrations:	control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg f.p./kg dry soil
Chemical analysis:	performed, samples of 5.04, 95.26 and 1000 mg/kg concentrations, sampled on days 0, 14 and 28
Statistical analysis:	EC <sub>10</sub> , EC <sub>20</sub> , and EC <sub>50</sub> – a probit method (NCSS) NOEC – ANOVA (GraphPad Prism 8)

## Findings

**Table: Summary of analytical method validation**

LOQ [ $\mu$ g as/L]	% recovery	Precision (%RSD)	Linearity ( $r^2$ )	Specificity
Not reported				

**Table: Analytical verification of the glyphosate concentration in test medium**

Test item concentration (mg/kg)	Nominal concentration of glyphosate (mg as/kg)	Analyzed concentration of glyphosate					
		Day 0		Day 14		Day 28	
		mg as/kg	% nominal	mg as/kg	% nominal	mg as/kg	% nominal
Control	0	-	-	-	-	-	-
5.04	2.24	2.208	98.6	2.208	98.6	2.210	98.7
95.26	42.345	41.579	98.2	41.588	98.2	41.609	98.6
1000.0	444.516	434.933	97.8	434.933	97.8	434.930	97.8

**Table: Summary of the test endpoints**

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]
LC <sub>50</sub>	>1000	>442.90
NOEC	171.47	75.94
EC <sub>10</sub>	398.21	176.31
EC <sub>20</sub>	>1000	>442.90
EC <sub>50</sub>	>1000	>442.90
NOEC	308.64	136.70
LOEC	555.56	246.06

**Table 5. Mortality of adult collembolans (*Folsomia candida*) after 28 days of the experiment.**

Sample/concentration [mg/kg d.w. soil]		Replicate	Number of tested collembolans	Number of living collembolans after 28 days	Total mortality	
					No.	%
Control	0.00	1	10	10	0	0.0
		2	10	10		
		3	10	10		
		4	10	10		
		5	10	10		
		6	10	10		
		7	10	10		
		8	10	10		
T1	5.04	1	10	10	0	0.0
		2	10	10		
		3	10	10		
		4	10	10		
T2	9.07	1	10	10	0	0.0
		2	10	10		
		3	10	10		
		4	10	10		
T3	16.33	1	10	10	0	0.0
		2	10	10		
		3	10	10		
		4	10	10		
T4	29.40	1	10	9	1	2.5
		2	10	10		
		3	10	10		
		4	10	10		
T5	52.92	1	10	10	0	0.0
		2	10	10		
		3	10	10		
		4	10	10		
T6	95.26	1	10	10	1	2.5
		2	10	10		
		3	10	9		
		4	10	10		
T7	171.47	1	10	9	1	2.5
		2	10	10		
		3	10	10		
		4	10	10		
T8	308.64	1	10	8	7	17.5 <sup>+</sup>
		2	10	8		
		3	10	8		
		4	10	9		
T9	555.56	1	10	7	11	27.5 <sup>+</sup>
		2	10	8		
		3	10	7		
		4	10	7		
T10	1000	1	10	6	17	42.5 <sup>+</sup>
		2	10	7		
		3	10	5		
		4	10	5		

+: statistically significant difference between the control and the treatment group at  $p < 0.05$

**Table 6. Endpoint values - the impact of the test item on the mortality of adult collembolans (*Folsomia candida*).**

Endpoint	Value [mg of the test item/kg d.w. soil]	Value [mg of active substance /kg d.w. soil]
LC <sub>10</sub>	167.75 (132.74 – 202.76)	74.30 (58.79 – 89.80)
LC <sub>20</sub>	389.94 (312.74 – 467.14)	172.70 (138.51 – 206.90)
LC <sub>50</sub>	>1000 (n.d.)	>442.90 (n.d.)
NOEC	171.47	75.94
LOEC	308.64	136.70

n.d. – not determined

**Table 7. Number of juvenile collembolans (*Folsomia candida*) after 28 days of the experiment.**

Sample/concentration [mg/kg d.w. soil]	Replicate	Number of juveniles	Mean ± SD	Reduction in comparison to the control [%]	CV* [%]
Control	1	732	778.00 ± 34.29	-	4.41
	2	775			
	3	798			
	4	731			
	5	801			
	6	830			
	7	790			
	8	767			
T1	1	795	777.00 ± 18.40	0.13	2.37
	2	755			
	3	789			
	4	769			
T2	1	787	777.50 ± 23.40	0.06	3.01
	2	743			
	3	795			
	4	785			
T3	1	756	768.00 ± 23.93	1.29	3.12
	2	798			
	3	775			
	4	743			
T4	1	797	767.25 ± 26.83	1.38	3.50
	2	760			
	3	778			
	4	734			
T5	1	739	770.50 ± 23.36	0.96	3.03
	2	780			
	3	769			
	4	794			
T6	1	756	758.25 ± 24.14	2.54	3.18
	2	740			
	3	793			
	4	744			
T7	1	790	751.25 ± 27.94	3.44	3.72
	2	728			
	3	753			
	4	734			
T8	1	778	735.50 ± 32.91	5.46	4.47
	2	701			
	3	742			
	4	721			
T9	1	759	716.00 <sup>+</sup> ± 39.08	7.97	5.46
	2	700			
	3	735			
	4	670			
T10	1	578	565.75 <sup>+</sup> ± 20.29	27.28	3.59
	2	555			
	3	543			
	4	587			

\*CV: coefficient of variation

+: statistically significant difference between the control and the treatment group at  $p < 0.05$

**Table 8. Endpoint values - the impact of the test item on reproduction of collembolans (*Folsomia candida*).**

Endpoint	Value [mg of the test item/kg d.w. soil]	Value [mg of active substance/kg d.w. soil]
EC <sub>10</sub>	398.21 (331.29 – 465.13 )	176.37 (146.73 – 206.01)
EC <sub>20</sub>	>1000 (n.d.)	>442.90 (n.d.)
EC <sub>50</sub>	>1000 (n.d.)	>442.90 (n.d.)
NOEC	308.64	136.70
LOEC	555.56	246.06

## Conclusions:

The EC<sub>10</sub> is 398.21 mg fp (176.31 mg as)/kg dw soil and NOEC is 308.64 mg fp (136.70 mg as)/kg dw soil.

Comments of zRMS:	<p>The study was conducted to OECD guideline 226 and according to the principles of GLP.</p> <p>The validity criteria of the test were met as:</p> <ul style="list-style-type: none"><li>- mortality in the control was 3.75% (a criterion: <math>\leq 20\%</math>)</li><li>- number of juveniles per replicate at the end of the test was 126.38 (criterion: <math>\geq 50</math>)</li><li>- coefficient of variation calculated for the number of juveniles was 9.85% (criterion: <math>\leq 30\%</math>)</li></ul> <p>The study is considered to be reliable and suitable for the risk assessment.</p>
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Reference: 10.4.2.1-2

Report: Effect of Glyphosate 54% SL on the reproductive output of the predatory soil mite *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in artificial soil, Angayarkanni V, 2020, 4854/2019

Guideline(s): Yes, OECD No. 226 (2016)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication  
(if vertebrate study): No

## Summary

The aim of the study was to assess the impact of Glyphosate 54% SL on mortality and reproductive output of the predatory soil mite, *Hypoaspis aculeifer*.

Mites were exposed to ten concentrations of the test item were used. These were 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg of the test item/kg of dry weight of the artificial soil.

Four replicates of 10 mites each were used per concentration; additionally 8 replicates of 10 mites each were used as an untreated control.

Effects of the test item were assessed after 14 days of exposure.

Samples of each of the test item concentrations of 5.04, 52.92 and 1000 mg/kg collected at exposure initiation and termination were chemically analyzed.

The determined concentration of glyphosate across the study were in the range of 97.8- 99.5% of the nominal concentration.

The endpoint values were determined based on the nominal test item concentrations as well as based on the nominal concentrations of active substances in the test item.

The EC<sub>10</sub> is 297.87 mg fp (131.93 mg as)/kg dw soil and NOEC is  $\geq 1000$  mg fp ( $\geq 442.90$  mg as)/kg dw

## Material and methods

Test item: Glyphosate 54% SL  
batch number: SCL-35984  
glyphosate (acid) content: 548 g/L  
manufacture date: March 19, 2018

expiry date:	March 18, 2020
Test organism:	The predatory mites, <i>Hypoaspis (Geolaelaps) aculeifer</i> (adult female) obtained from BFR Insectary.
Test design:	Number of replicates: 4 replicates/concentration + 8 replicates/control Number of mites: 10 mites/replicate
Artificial soil:	5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand
Test conditions:	Temperature: 20.3- 21.7°C pH at the beginning of the test: 5.96- 6.25 pH at the end of the test: 6.34- 6.37 Soil moisture content at the beginning of the test: 20.24- 21.32% (51.54- 52.53 %MWHC) Soil moisture content at the end of the test: 18.97- 19.98% (49.16- 50.03 %MWHC) Lighting: 16 h light and 8 h dark Light intensity: 440 – 620 Lx
Test duration:	14 days
Test item concentrations:	control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg/kg dry weight of soil
Chemical analysis:	performed, samples of 5.04, 52.92 and 1000 mg/kg concentrations, sampled on days 0, 7 and 14
Statistical analysis:	The endpoint values for mortality and reproduction were determined by using a Probit analysis in the NCSS and one-way ANOVA using Graphpad Prism 8.0.

## Findings

**Table: Summary of analytical method validation**

LOQ [ $\mu\text{g as/L}$ ]	% recovery	Precision (%RSD)	Linearity ( $r^2$ )	Specificity
Not reported				

**Table: Analytical verification of the glyphosate concentration in test medium**

Test item concentration (mg/kg)	Nominal concentration of glyphosate (mg as/kg)	Analyzed concentration of glyphosate					
		Day 0		Day 14		Day 28	
		mg as/kg	% nominal	mg as/kg	% nominal	mg as/kg	% nominal
Control	0	0	100	0	100	0	100
5.04	2.24	2.202	98.3	2.195	98.0	2.191	97.8
52.92	23.524	23.268	98.9	23.346	99.2	23.288	99.0
1000.0	444.516	442.448	99.5	441.505	99.3	440.490	99.1

**Table: Summary of the test endpoints**

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]
LC <sub>50</sub>	>1000	>442.90
NOEC	171.47	75.94
EC <sub>10</sub>	297.87	131.93
EC <sub>20</sub>	>1000	>442.90
EC <sub>50</sub>	>1000	>442.90
NOEC	>1000	>442.90
LOEC	>1000	>442.90

**Table 5. Summarised results of mortality of adult females after 14 days of exposure to the test soil.**

Sample	Concentration [mg of test item/kg d.w. soil]	Total number of adult females introduced	Total number of non- recovered adult females	Mean Mortality [%]	SD	SE	Mortality corrected for control [%] <sup>+</sup>
C	0.00	80	3	3.75	5.18	1.83	--
T1	5.04	40	2	5.0	5.77	2.89	1.30
T2	9.07	40	3	7.5	9.57	4.79	3.90
T3	16.33	40	4	10.0	8.16	4.08	6.49
T4	29.40	40	4	10.0	8.16	4.08	6.49
T5	52.92	40	5	12.5	5.00	2.50	9.09
T6	95.26	40	6	15.0	5.77	2.89	11.69
T7	171.47	40	7	17.5	9.57	4.79	14.29
T8	308.64	40	8	20.0	8.16	4.08	16.88 <sup>+</sup>
T9	555.56	40	9	22.5	9.57	4.79	19.48 <sup>+</sup>
T10	1000.00	40	14	35.0	10.00	5.00	32.47 <sup>+</sup>
Endpoint	Value [mg test item/kg d.w. soil]		Value [mg of active substance/kg d.w. soil]				
LC <sub>10</sub>	<b>70.12</b> (54.48 – 85.76)		<b>31.06</b> (24.13 – 37.98)				
LC <sub>20</sub>	<b>370.26</b> (281.58 – 458.94)		<b>163.99</b> (124.71 – 203.26)				
LC <sub>50</sub>	> <b>1000</b> (n.d.)		> <b>442.90</b> (n.d.)				
NOEC	<b>171.47</b>		<b>75.94</b>				
LOEC	<b>308.64</b>		<b>136.70</b>				

SD: standard deviation,

SE: standard error

\*: Mortality corrected according to Abbott's formula:

Corrected mortality [%] = ((Mt - Mc) ÷ (100 - Mc)) × 100; Mt = Mortality treated, Mc = Mortality control

+: statistically significant difference between the control and the treatment group

n.d. - not determined



**Table 7. Summarised results of reproductive output of *Hypoaspis aculeifer* after 14 days of exposure to the test soil**

Sample	Concentration [mg of test item/kg d.w. soil]	Mean number of juveniles	SD	SE	CV [%]	Reduction in reproduction output compared to control [%]
C	0.00	126.38	12.45	4.40	9.85	--
T1	5.04	123.75	14.31	7.16	11.56	2.08
T2	9.07	123.00	22.69	11.35	18.45	2.67
T3	16.33	122.25	5.56	2.78	4.55	3.27
T4	29.40	120.00	2.94	1.47	2.45	5.05
T5	52.92	119.25	7.27	3.64	6.10	5.64
T6	95.26	118.50	2.89	1.45	2.44	6.24
T7	171.47	117.25	9.98	4.99	8.51	7.22
T8	308.64	115.75	8.54	4.27	7.38	8.41
T9	555.56	111.25	7.46	3.73	6.71	11.97
T10	1000.00	105.00	11.52	5.76	10.97	16.92
Endpoint	Value [mg test item/kg d.w. soil]		Value [mg of active substance/kg d.w. soil]			
EC <sub>10</sub>	<b>297.87</b> (189.35 – 406.39)		<b>131.93</b> (83.86 – 179.99)			
EC <sub>20</sub>	<b>&gt; 1000</b> (n.d.)		<b>&gt; 442.90</b> (n.d.)			
EC <sub>50</sub>	<b>&gt; 1000</b> (n.d.)		<b>&gt; 442.90</b> (n.d.)			
NOEC	<b>≥ 1000</b>		<b>≥ 442.90</b>			
LOEC	<b>&gt; 1000</b>		<b>&gt; 442.90</b>			

SD: standard deviation,  
SE: standard error,  
CV: coefficient of variation  
n.d. - not determined

#### Conclusions:

The EC<sub>10</sub> is 297.87 mg fp (131.93 mg as)/kg dw soil and NOEC is ≥1000 mg fp (≥442.90 mg as)/kg dw

#### A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

#### A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	<p>The study was conducted to OECD guideline 216 and according to the principles of GLP. All the validity criterion was met as:</p> <ul style="list-style-type: none"> <li>- the coefficients of variation (CV) in the control group were 10.6, 11.9, 6.9, and 3.1%, after 0, 7, 14, and 28 days of incubation (criterion: less than ± 15%).</li> </ul> <p>The study is considered to be reliable and suitable for the risk assessment.</p>
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Reference:

KCP 10.5-1

Report	Glyphosate 54% SL. Soil Microorganisms: Nitrogen Transformation Test, Dec W. 2019, report No. G/06/18
Guideline(s):	Yes, OECD 216 (2000)
Deviations:	No
GLP:	Yes
Acceptability:	YES
Duplication (if vertebrate study)	No

The aim of the study was to detect long-term adverse effects of Glyphosate 54% SL on the processes of nitrogen transformation in aerobic surface soils (agricultural soil, manually cleared of large objects and sieved to a particle size of 2 mm).

The concentrations of the test item were 28.80 mg of the test item/kg dw soil and 143.99 mg of the test item/kg dw soil (12.79 and 63.93 mg of glyphosate/kg of dw soil), corresponding to maximum PEC (predicted environmental concentration) and 5 x PEC.

The treated and the control soils were divided into three replicates. On days 0, 7, 14, and 28 of incubation, soil samples were collected to determine the quantities of nitrate.

The method involved a measurement of the nitrates ions concentration in a soil extract obtained by using 0.1 M KCl. The pH/ION 7320 digital meter and the NO 800 nitrate electrode were used. The nitrate formation rate in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated.

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC and 5 x PEC did not exceed 25% on 28 day of analysis.

### Materials and methods:

Test material:	Glyphosate 54% SL batch number: SCL-35984 glyphosate (acid) content: 548 g/L manufacture date: March 19, 2018 expiry date: March 18, 2020
Soil:	sandy clay loam soil, collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna (49°59', 780N and 18°55', 190E).
Test design:	control group and two treated groups, 3 replicates/ group the soil was enriched with the organic substrate, lucerne, 5 g/kg dry weight of soil.
Test duration:	28 days.
Concentrations of the test item: control	PEC: 28.80 mg fp (12.79 glyphosate)/kg dw soil 5 x PEC: 143.99 mg fp (63.93 mg glyphosate)/kg dw soil
Test conditions:	temperature: 18.0 – 20.50°C soil moisture: 42.4- 51.6% MWHC incubation in darkness
Endpoints:	- the concentration of nitrate [mg/kg dry soil] after 0, 7, 14, and 28 days of incubation - the nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 - 7, 0 – 14, 0 – 28 days. - percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 - 7, 0 – 14, 0 – 28 days.

Statistical analysis: - Shapiro-Wilk's test on Normal Distribution  
- Levene's Test on Variance Homogeneity (with Residuals)  
- Williams Multiple Sequential t-test Procedure

## Results

	Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals			Deviations from the control based on nitrate formation rate [%]		
	Time interval [days]					
	0-7	0-14	0-28	0-7	0-14	0-28
Control	14.773±4.0	7.549±1.16	9.280±0.44			
PEC	13.594±1.11	8.667±0.28	9.991±0.5	8.0	-14.7	-7.7
5 x PEC	10.825±0.8	7.263±0.77	8.358±0.65	26.7	3.8	9.9

## Conclusions

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC and 5 x PEC did not exceed 25% on 28 day of analysis.

It was concluded that Glyphosate 54% SL at the concentration corresponding to the PEC and 5 x PEC did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Comments of zRMS:	Since Carbon Transformation Test is no longer data requirement, thus the study was not evaluated by zRMS.
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Reference:	KCP 10.5-2
Report	Glyphosate 54% SL. Soil Microorganisms: Carbon Transformation Test, Dec W, 2019, report No. G/05/18
Guideline(s):	Yes, OECD 214 (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

The aim of the study was to detect long-term adverse effects of Glyphosate 54% SL on the processes of carbon transformation in aerobic surface soils (agricultural soil, manually cleared of large objects and sieved to a particle size of 2 mm).

The concentrations of the test item were 28.80 mg of the test item/kg dw soil and 143.99 mg of the test item/kg dw soil (12.79 and 63.93 mg of glyphosate/kg of dw soil), corresponding to maximum PEC (predicted environmental concentration) and 5 x PEC.

The soil incubation time was 28 days. On 0, the 7th, 14th and 28th day of incubation, the respiration rates in the treated and control soil samples were determined. The Substrate-Induced Respiration (SIR) method was used to determine the intensity of soil respiration [SOP/G/33]. It involved measurements of the pressure difference in a closed system. During respiration, expelled carbon dioxide was bound to an absorbent (a 45% water solution of KOH). It led to a pressure-drop which was proportional to soil respiration. The mean oxygen consumption recorded in case of the treated samples during carbon transformations was compared with that in the control, and the percentage deviation from the control was calculated.

The difference in the soil respiration rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC and 5 x PEC did not exceed 25% on 28 day of analysis.

#### Materials and methods:

Test material:	Glyphosate 54% SL batch number: SCL-35984 glyphosate (acid) content: 548 g/L manufacture date: March 19, 2018 expiry date: March 18, 2020
Soil:	sandy clay loam soil, collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna (49°59', 780N and 18°55', 190E).
Test design:	control group and two treated groups, 3 replicates/ group the soil was enriched with the organic substrate, lucerne, 5 g/kg dry weight of soil.
Test duration:	28 days.
Concentrations of the test item:	control PEC: 28.80 mg fp (12.79 glyphosate)/kg dw soil 5 x PEC: 143.99 mg fp (63.93 mg glyphosate)/kg dw soil
Test conditions:	temperature: 18.0 – 20.50°C soil moisture: 44.7- 50.3% MWHC incubation in darkness
Endpoints:	The mean respiration rate in the treated soil samples was compared with that in the control, and the percent deviation of the treated from the control was calculated after 0, 7, 14, and 28 days of incubation
Statistical analysis:	- Shapiro-Wilk's test on Normal Distribution - Levene's Test on Variance Homogeneity (with Residuals) - Williams Multiple Sequential t-test Procedure

#### Results

	Pressure values determined during respiration measurements [hPa/12 hours]				O <sub>2</sub> consumption [mg/kg dry weight soil/hour]				O <sub>2</sub> consumption - deviations from the control [%]			
	Day				Day				Day			
	0	7	14	28	0	7	14	28	0	7	14	28
Control	46.0	20.3	23.3	27.0	32.1	14.1	16.1	18.8	-	-	-	-
PEC	47.0	22.3	18.7	23.0	32.8	15.5	12.9	16.0	-2.3	-9.7	20.1	14.7
5 x PEC	47.0	19.0	18.3	24.3	32.5	13.1	12.6	16.8	-1.6	7.3	21.7	10.6

#### Conclusions

The difference in the soil respiration rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC and 5 x PEC did not exceed 25% on 28 day of analysis.

It was concluded that Glyphosate 54% SL at the concentration corresponding to the PEC and 5 x PEC did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

## A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

### A 2.6.1 KCP 10.6.1 Summary of screening data

## A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study on effects on the vegetative vigour of ten non-target terrestrial plant species was performed in line with requirements of OECD 227 and according to the principles of GLP. All the validity criteria were fulfilled. The study is reliable and suitable for the risk assessment.
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Reference:	KCP 10.6.2-01
Report	“Effect of Glyphosate 54% SL on vegetative vigour of terrestrial plants. Dr. S. Radha. 2021. Study code: 9042/2021. Bioscience Research Foundation.
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	Yes, Three seeds were used in the area of 16 cm, this did not affect the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

### Materials and methods

Test item:	Glyphosate 54% SL; Batch Number: SCL-42130; active substance content: Glyphosate, 551 g/l
Test species:	Soybean ( <i>Glycine max</i> ), tomato ( <i>Solanum lycopersicon</i> ), Radish ( <i>Raphanus sativus</i> ), corn ( <i>Zea mays</i> ), Oats ( <i>Avena sativa</i> ) and Onion ( <i>Allium cepa</i> ).
Soil:	Sandy loam soil, 1.1% organic carbon, 2 mm particle size
Study design:	Number of rates: 5 application rates + control; number of replicates: 7 replicates/rate. The total number of plants per application rate – 21. Test termination: 21 days after the application of the test item.
Application rates:	Control, 0.0125, 0.025, 0.05, 0.1 and 0.2 L/ha (6.9, 13.8, 27.6, 55.1 and 110.2 g Glyphosate/ha). Volume of distilled water used to prepare the highest rate: 300 L water/ha.
Test conditions:	Temperature: 21.0 – 22.1°C, humidity: 57.0 – 67.5%, controlled light – dark cycles (16h:8h), light intensity: 342 – 400 $\mu\text{E}/\text{m}^2/\text{s}$ , carbon dioxide concentration: 327 – 345 ppm.
Statistical analysis:	ER <sub>10</sub> , ER <sub>25</sub> , ER <sub>50</sub> and NOER values were determined by using a Probit analysis in the NCSS and one-way ANOVA using Graph Pad Prism 8.0
Endpoints:	ER <sub>10</sub> , ER <sub>25</sub> , ER <sub>50</sub> , NOER

The study was carried out based on the Sponsor recommended rates for the test item as the definite test. Five application rates were used. There was also a concurrent control group. The study groups were as follows:

Groups	Rates of the test item (L/ha)	Rates of Glyphosate* (g/ha)
Control group	0.0	0.0
Test item group I	0.0125	6.9
Test item group II	0.025	13.8
Test item group III	0.05	27.6
Test item group IV	0.1	55.1
Test item group V	0.2	110.2

\*: based on the Glyphosate content in the test item, i.e. 551g/l provided by the Sponsor

Seeds of the test plant species were sown in plastic pots. The plants were grown to the 2- to 4-true leaf stage. Then, some of them were removed. As a result, the number of plants per pot as well as the total number of plants per application rate was 3 plants/pot, i.e. 21 plants/application rate (7 pots/application rate) for soybean, corn, onion, oats, radish and tomato. The number of plants per pot selection provided the adequate growth conditions and avoided overcrowding during the experiment. The test item was sprayed onto the plant leaf surface. The experiment was conducted in a plant growth chamber with suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application) and mortality. The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60°C to a constant weight and weighed.

The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER10, ER25, ER50 and NOER values.

Six plant species belonging to *Monocotyledonae* and *Dicotyledonae* classes were used. There were soybean (*Glycine max*), corn (*Zea mays*), radish (*Raphanus sativus*), onion (*Allium cepa*), tomato (*Solanum lycopersicon*) and oats (*Avena sativa*). The test species were selected from the list given in OECD Guideline No. 227 (2006). Only certified seeds of the plants obtained from known source were used for the study. Before the experiment, seeds had been kept under dry conditions. The seed viability was also evaluated before the experiment. Seeds were soaked briefly in a weak 5% hypochlorite solution, then rinsed extensively in running water and dried. The general characteristics of the test species is presented in Table below.

Plant species	Family	Source	Batch No.	Seed viability (%)
<b>Class: <i>Dicotyledonae</i></b>				
Soybean ( <i>Glycine max</i> )	Fabaceae(Leguminosae)	Namdhari Seeds Pvt Ltd.	A-5423-29-34	92
Tomato ( <i>Solanum lycopersicon</i> )	Solanaceae	Namdhari Seeds Pvt Ltd.	T5524-12-53	91
Radish ( <i>Raphanus sativus</i> )	Brassicaceae (Cruciferae)	Namdhari Seeds Pvt Ltd.	S1764-23-56	90
<b>Class: <i>Monocotyledonae</i></b>				
Corn ( <i>Zea mays</i> )	Poaceae (Gramineae)	Namdhari Seeds Pvt Ltd.	C11452-0202-001	85
Oats ( <i>Avena sativa</i> )	Poaceae (Gramineae)	Namdhari Seeds Pvt Ltd.	S1764-23-56	90
Onion ( <i>Allium cepa</i> )	Liliaceae (Amaryllidaceae)	Namdhari Seeds Pvt Ltd.	C1654-24-59	91

## Results

The test item, i.e. **Glyphosate 54% SL** applied at rates ranging from 0.0125 to 0.2 L/ha of the test item/ha, had a varied impact on vegetative vigour of all the plant species tested. The impact depended on the rate of test item and species used.

There was mortality observed for all the plant species tested at rates ranging from 0.0125 to 0.2 L/ha of the test item/ha. The phytotoxic symptoms for plant species tested were observed at rates of 0.025 to 0.2 L/ha of the test item used. The following phytotoxic symptoms were observed on 21 days after the test item application: chlorosis, necrosis, wilting, leaf deformation, stem deformation or death.

Plant growth and development could be directly affected by the pesticides applied on them. The vegetative vigour test is a test that evaluates the effect of a test substance upon the growth of the plant. The purpose of the present study is to assess the potential effect of test substance on the leaves and above-ground portions of the plant. The growth inhibition rates are expressed as ER<sub>50</sub>.

**Table 12.Corn (*Zea mays*) - plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0.0	R1	0	0.0	N	0	0.0	N	0	0.0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.0125	R1	0	0.0	N	0	0.0	N	0	0.0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.025	R1	0	0.0	N	0	0.0	N	0	0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.05	R1	0	0.0	N	0	3.57	N, C, Ld	0	5	N, C, Ld
	R2	0			10			15		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			15			20		
	R7	0			0			0		
0.1	R1	10	5.71	N,C, Ld	15	10	N, C, Ld	20	14.28	N, C, Ld, Sd
	R2	5			10			15		
	R3	10			15			20		
	R4	0			5			10		
	R5	5			10			15		
	R6	10			15			20		
	R7	0			0			0		
0.2	R1	15	11.43	C, Ld	20	16.43	C, Ld, Sd	25	22.14	C, Ld, Sd, Ne
	R2	10			15			20		
	R3	10			15			25		
	R4	10			15			20		
	R5	5			10			15		
	R6	15			20			25		
	R7	15			20			25		

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead

\*: all plants dead



**Table 16. Onion (*Allium cepa*) - plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects								
		Day 7		Day 14		Day 21				
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms			
0.0	R1	0	0.0	N	0	0.0	N	0	0.0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.0125	R1	0	0.0	N	0	0.0	N	0	0.0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.025	R1	0	0.0	N	0	0.0	N	0	1.43	N
	R2	0			0			5		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			5		
	R6	0			0			0		
	R7	0			0			0		
0.05	R1	0	2.86	N, C	0	5.0	N, C	0	7.14	N, C, Ld
	R2	5			10			15		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			5			10		
	R6	15			20			25		
	R7	0			0			0		
0.1	R1	0	4.29	N, C	0	7.14	N, C, Ld	0	11.43	N, C, Ld, Sd
	R2	0			5			10		
	R3	10			15			20		
	R4	5			10			15		
	R5	0			0			5		
	R6	15			20			30		
	R7	0			0			0		
0.2	R1	15	16.0	C, Ld	20	21.0	C, Ld, Sd, Ne	25	26.0	C, Ld, Sd, W
	R2	10			15			20		
	R3	20			25			30		
	R4	-*			-*			-*		
	R5	15			20			25		
	R6	-*			-*			-*		
	R7	20			25			30		

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead  
\*: all plants dead

**Table 20.Oats (*Avena sativa*)-plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0.0	R1	0	0.00	N	0	0.00	N	0	0.00	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.0125	R1	0	0.0	N	0	0.0	N	0	0.0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.025	R1	0	0.0	N	0	0.0	N	0	2.14	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			10		
	R5	0			0			0		
	R6	0			0			5		
	R7	0			0			0		
0.05	R1	0	3.57	N, C	0	6.43	N, C	5	10	N,C
	R2	0			5			10		
	R3	0			0			0		
	R4	5			10			15		
	R5	10			15			20		
	R6	0			0			0		
	R7	10			15			20		
0.1	R1	10	9.29	N, C	15	14.29	N, C	20	19.29	N, C, Ld
	R2	0			5			10		
	R3	10			15			20		
	R4	5			10			15		
	R5	15			20			25		
	R6	10			15			20		
	R7	15			20			25		
0.2	R1	15	19.0	C, Ld	20	24.0	C, Ld, Sd	25	29.0	C, Ld, Sd, Ne
	R2	_*			_*			_*		
	R3	25			30			35		
	R4	20			25			30		
	R5	15			20			25		
	R6	20			25			30		
	R7	_*			_*			_*		

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead

\*: all plants dead



**Table 24.Radish (*Raphanus sativus*)-plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects								
		Day 7		Day 14		Day 21				
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms			
0.0	R1	0	0.0	N	0	0.0	N	0	0.0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.0125	R1	0	0.0	N	0	0.0	N	0	0.0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.025	R1	0	0.0	N	0	0.0	N	0	0.0	N
	R2	0			0			0		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
0.05	R1	0	0.0	N	0	0.0	N	0	2.14	N,C
	R2	0			0			5		
	R3	0			0			0		
	R4	0			0			0		
	R5	0			0			10		
	R6	0			0			0		
	R7	0			0			0		
0.1	R1	0	7.86	N, C	0	12.14	N,C, Ld	5	17.14	C, Ld, Sd
	R2	10			15			20		
	R3	5			10			15		
	R4	5			10			15		
	R5	10			15			20		
	R6	15			20			25		
	R7	10			15			20		
0.2	R1	15	13.33	C, Ld	20	18.33	C, Ld, Sd	25	25.83	C, Ld, Sd, W
	R2	10			15			20		
	R3	10			15			30		
	R4	20			25			35		
	R5	20			25			30		
	R6	_*			_*			_*		
	R7	5			10			15		

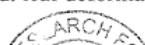
N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead  
\*: all plants dead

**Table 28. Tomato (*Solanum lycopersicon*)-plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects							
		Day 7		Day 14		Day 21			
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms		
0.0	R1	0	0.0 N	0	0.00 N	0	0.0 N		
	R2	0		0		0			
	R3	0		0		0			
	R4	0		0		0			
	R5	0		0		0			
	R6	0		0		0			
	R7	0		0		0			
0.0125	R1	0	0.0 N	0	0.0 N	0	0.0 N		
	R2	0		0		0			
	R3	0		0		0			
	R4	0		0		0			
	R5	0		0		0			
	R6	0		0		0			
	R7	0		0		0			
0.025	R1	0	0.0 N	0	0.0 N	0	0.0 N		
	R2	0		0		0			
	R3	0		0		0			
	R4	0		0		0			
	R5	0		0		0			
	R6	0		0		0			
	R7	0		0		0			
0.05	R1	0	0.0 N	0	0.0 N	0	1.43 N, C		
	R2	0		0		0			
	R3	0		0		5			
	R4	0		0		5			
	R5	0		0		0			
	R6	0		0		5			
	R7	0		0		0			
0.1	R1	0	6.43 N, C	5	10.71 N,C, Ld	10	15.71 N,C, Ld		
	R2	10		15		25			
	R3	10		15		20			
	R4	0		0		0			
	R5	15		20		25			
	R6	10		15		20			
	R7	0		5		10			
0.2	R1	10	12.86 C, Ld	15	18.57 C, Ld	20	22.86 C, Ld, Sd, Ne		
	R2	15		20		25			
	R3	10		15		20			
	R4	15		20		30			
	R5	15		25		25			
	R6	10		15		35			
	R7	15		20		25			

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead

\*: all plants dead



**Table 29.Endpoint values - the impact of the test item on vegetative vigour of plants.**

Endpoint value with 95% CL		Soybean ( <i>Glycine max</i> )	Corn ( <i>Zea mays</i> )	Onion ( <i>Allium cepa</i> )	Oats ( <i>Avena sativa</i> )	Radish ( <i>Raphanus sativus</i> )	Tomato ( <i>Solanum lycopersicon</i> )
Plant number							
ER <sub>10</sub>	L/ha <sup>a</sup>	0.013 (0.011 - 0.015)	0.013 (0.011- 0.015)	<0.0125	<0.0125	0.016 (0.014- 0.018)	0.015 (0.013- 0.017)
	g a.i./ha	7.2 (6.1 – 8.3)	7.2 (6.1-8.3)	<6.9	<6.9	8.8 (7.7-9.9)	8.3 (7.2-9.4)
ER <sub>25</sub>	L/ha <sup>a</sup>	0.030 (0.027- 0.033)	0.033 (0.029- 0.037)	0.024 (0.021- 0.027)	0.023 (0.020- 0.026)	0.035 (0.032- 0.038)	0.035 (0.031- 0.039)
	g a.i./ha	16.5 (14.9- 18.2)	18.2 (16.0-20.4)	13.2 (11.6- 14.9)	12.7 (11.0-14.3)	19.3 (17.6- 20.9)	19.3 (17.1-21.5)
ER <sub>50</sub>	L/ha <sup>a</sup>	0.072 (0.066 - 0.078)	0.092 (0.083- 0.101)	0.061 (0.056- 0.066)	0.058 (0.053- 0.063)	0.084 (0.077- 0.091)	0.089 (0.080- 0.098)
	g a.i./ha	39.7 (36.4- 43.0)	50.7 (45.7-55.7)	33.6 (30.9- 36.4)	32.0 (29.2- 34.70)	46.3 (42.4- 50.1)	49.0 (44.1-54.0)
NOER	L/ha <sup>a</sup>	0.025	0.0125	0.0125	0.0125	0.025	0.025
	g a.i./ha	13.8	6.9	6.9	6.9	13.8	13.8
Shoot length (plants without roots)							
ER <sub>10</sub>	L/ha <sup>a</sup>	0.016 (0.014- 0.0180)	0.017 (0.015- 0.019)	0.013 (0.011- 0.015)	<0.0125	<0.0125	0.014 (0.012- 0.016)
	g a.i./ha	8.8 (7.7-9.9)	9.4 (8.3-10.5)	7.2 (6.1-8.3)	<6.9	<6.9	7.7 (6.6-8.8)
ER <sub>25</sub>	L/ha <sup>a</sup>	0.033 (0.030- 0.036)	0.037 (0.034- 0.040)	0.028 (0.025- 0.031)	0.024 (0.022- 0.027)	0.029 (0.026- 0.032)	0.032 (0.029- 0.035)
	g a.i./ha	18.2 (16.5- 19.8)	20.4 (18.7- 22.0)	15.4 (13.8- 17.1)	13.2 (11.8-14.6)	16.0 (14.3- 17.6)	17.6 (16.0-19.3)

<b>ER<sub>50</sub></b>	L/ha <sup>a</sup>	0.074 (0.068-0.080)	0.087 (0.079-0.095)	0.064 (0.059-0.069)	0.057 (0.052-0.062)	0.075 (0.068-0.082)	0.083 (0.075-0.091)
	g a.i./ha	40.8 (37.5-44.1)	47.9 (43.5-52.3)	35.3 (32.5-38.0)	31.4 (28.7-34.2)	41.3 (37.5-45.2)	45.7 (41.3 - 50.1)
<b>NOER</b>	L/ha <sup>a</sup>	0.0125	0.0125	0.0125	0.0125	0.0125	0.0125
	g a.i./ha	6.9	6.9	6.9	6.9	6.9	6.9
<b>Plant dry weight (plants without roots)</b>							
<b>ER<sub>10</sub></b>	L/ha <sup>a</sup>	0.013 (0.011-0.015)	0.014 (0.012-0.016)	<0.0125	<0.0125	<0.0125	<0.0125
	g a.i./ha	7.2 (6.1-8.3)	7.7 (6.6-8.8)	<6.9	<6.9	<6.9	<6.9
<b>ER<sub>25</sub></b>	L/ha <sup>a</sup>	0.028 (0.025-0.031)	0.032 (0.029-0.035)	0.026 (0.023-0.029)	0.026 (0.023-0.029)	0.027 (0.024-0.030)	0.029 (0.026-0.032)
	g a.i./ha	15.4 (13.8-17.1)	17.6 (16.0-19.3)	14.3 (12.7-16.0)	14.3 (12.7-16.0)	14.9 (13.2-16.5)	16.0 (14.3-17.6)
<b>ER<sub>50</sub></b>	L/ha <sup>a</sup>	0.063 (0.058-0.068)	0.078 (0.071-0.085)	0.062 (0.057-0.067)	0.060 (0.055-0.065)	0.072 (0.065-0.079)	0.078 (0.071-0.085)
	g a.i./ha	34.7 (32.0-37.5)	43.0 (39.1-46.8)	34.2 (31.4-36.9)	33.1 (30.3-35.8)	39.7 (35.8-43.5)	43.0 (39.1-46.8)
<b>NOER</b>	L/ha <sup>a</sup>	0.0125	0.0125	0.0125	0.0125	0.0125	0.0125
	g a.i./ha	6.9	6.9	6.9	6.9	6.9	6.9

<sup>a</sup>: value for the test item, i.e. Glyphosate 54% SL expressed as L/ha

<sup>b</sup>: value for active substance, i.e Glyphosate 54% SL expressed as g/ha

The following validity criteria were met:

- the seedling emergence (validity criterion: at least 70%) was as follows:
  - 100% – soybean,
  - 100% – corn,
  - 100% – onion,
  - 100%– radish,
  - 100%– oats,
  - 100%– tomato,
- the mean survival of the emerged control seedlings was 100% in case of all experimental species (validity criterion: at least 90%),
- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

## Results and Conclusions

The test item Glyphosate 54% SL applied at rates ranging from 0.0125 to 2 L test item/ha had a varied impact on vegetative vigour of all plant species.

There was mortality observed for all the plant species at rates ranging from 0.0125 to 0.2 L test item/ha. The phytotoxic symptoms for all the plant species tested were observed at the rates of 0.025 to 0.2 L/ha. The following symptoms were observed on 21 days after the test item application: Chlorosis, necrosis, wilting, leaf deformation, stem deformation or death.

**Table 4 - Endpoint values – Vegetative vigour**

Endpoint Value (L/ha <sup>a</sup> )		Soybean ( <i>Glycine max</i> )	Corn ( <i>Zea mays</i> )	Onion ( <i>Allium cepa</i> )	Oats ( <i>Avena sativa</i> )	Radish ( <i>Raphanus sativus</i> )	Tomato ( <i>Solanum lycopersicon</i> )
<b>Plant number at the end of the experiment</b>							
<b>ER<sub>50</sub></b>	L/ha <sup>a</sup>	<b>0.072</b> (0.066 – 0.078)	<b>0.092</b> (0.083 – 0.101)	<b>0.061</b> (0.056 – 0.066)	<b>0.058</b> (0.053 – 0.063)	<b>0.084</b> (0.077 – 0.091)	<b>0.089</b> (0.080 – 0.098)
	g/ha <sup>b</sup>	<b>39.7</b> (36.4 – 43.0)	<b>40.7</b> (45.7 – 55.7)	<b>33.6</b> (30.9 – 36.4)	<b>32.0</b> (29.2 – 34.7)	<b>46.3</b> (42.4 – 50.1)	<b>49.0</b> (44.1 – 54.0)
<b>NOER</b>	L/ha <sup>a</sup>	<b>0.025</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>
	g/ha <sup>b</sup>	<b>13.8</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>
<b>Shoot length (plants without roots)</b>							
<b>ER<sub>50</sub></b>	L/ha <sup>a</sup>	<b>0.074</b> (0.068 – 0.080)	<b>0.087</b> (0.079 – 0.095)	<b>0.064</b> (0.059 – 0.069)	<b>0.057</b> (0.052 – 0.062)	<b>0.075</b> (0.068 – 0.082)	<b>0.083</b> (0.075 – 0.091)
	g/ha <sup>b</sup>	<b>40.8</b> (37.5 – 44.1)	<b>47.9</b> (43.5 – 52.3)	<b>35.3</b> (32.5 – 38.0)	<b>31.4</b> (28.7 – 34.2)	<b>41.3</b> (37.5 – 45.2)	<b>45.7</b> (41.3 – 50.1)
<b>NOER</b>	L/ha <sup>a</sup>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>
	g/ha <sup>b</sup>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>
<b>Plant dry weight (plants without roots)</b>							
<b>ER<sub>50</sub></b>	L/ha <sup>a</sup>	<b>0.063</b> (0.058 – 0.068)	<b>0.078</b> (0.071 – 0.085)	<b>0.062</b> (0.057 – 0.067)	<b>0.060</b> (0.055 – 0.065)	<b>0.072</b> (0.065 – 0.079)	<b>0.078</b> (0.071 – 0.085)
	g/ha <sup>b</sup>	<b>34.7</b>	<b>43.0</b>	<b>34.2</b>	<b>33.1</b>	<b>39.7</b>	<b>43.0</b>

		(32.0 – 37.5)	(39.1 – 46.8)	(31.4 – 36.9)	(30.3 – 35.8)	(35.8 – 43.5)	(39.1 – 46.8)
<b>NOER</b>	L/ha <sup>a</sup>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>	<b>0.0125</b>
	g/ha <sup>b</sup>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>	<b>6.9</b>

a: value for the test item i.e. Glyphosate 54% SL expressed as L/ha

b: Value for the active substance, i.e Glyphosate expressed as g/ha

Comments of zRMS:	The study on the Effects on the seedling emergence and growth on non-target terrestrial plant species was performed in line with requirements of OECD 208 and according to the principles of GLP. All the validity criteria were fulfilled. The study is reliable and suitable for the risk assessment.
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Reference:	KCP 10.6.2-02
Report	“Effect of Glyphosate 54% SL on seedling emergence and seedling growth of terrestrial plants”. Dr. S. Radha, 2021. Study code: 9041/2021. Bioscience Research Foundation
Guideline(s):	OECD Guideline No. 208 (2006)
Deviations:	Yes, Three seeds were used in the area of 16 cm, this did not affect the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

## Materials and methods

Test item:	Glyphosate 54% SL; Batch Number SCL - 42130; active substance content: Glyphosate, 551 g/l
Test species:	Soybean ( <i>Glycine max</i> ), tomato ( <i>Solanum lycopersicon</i> ), Radish ( <i>Raphanus sativus</i> ), corn ( <i>Zea mays</i> ), Oats ( <i>Avena sativa</i> ) and Onion ( <i>Allium cepa</i> ).
Soil:	Sandy loam soil, 1.1% organic carbon, 2 mm particle size
Study design:	Number of concentrations: 5 application rates + a control Number of replicates: 7 replicates of each application rate and the control Number of seeds: 3 seeds/replicate Test termination: 14 days after the emergence of 50% of the control seedlings
Application rates:	Control, 1.5, 3, 6, 12 and 24 L test item/ha (827, 1653, 3306, 6612 and 13224 g Glyphosate/ha). Volume of distilled water used to prepare the highest rate: 300 L water/ha.
Test conditions:	Temperature: 21.5– 22.4 °C; humidity: 59.2 – 69.3%; lighting: 16 h light : 8 h dark; light intensity: 326 – 400 µE/m <sup>2</sup> /s; carbon dioxide concentration: 331 – 342 ppm
Statistical analysis:	ER <sub>10</sub> , ER <sub>25</sub> , ER <sub>50</sub> and NOER – Probit in the NCSS and one-way ANOVA using GraphPad Prism 8.0, respectively
Endpoints:	ER <sub>10</sub> , ER <sub>25</sub> , ER <sub>50</sub> , NOER

The study, aimed at evaluating the effect of **Glyphosate 54% SL** on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 3 dicotyledonous and 3 monocotyledonous species to determine the ER<sub>10</sub>, ER<sub>25</sub>, ER<sub>50</sub>, and NOER values for plant number, shoot length and shoot weight. The study was conducted for Sharda Cropchem Ltd, India at Bioscience Research Foundation, India according to the OECD guideline No. 208, Adopted 19<sup>th</sup> July, 2006 and the study plan.

The study was carried out based on the Sponsor recommended rates for the test item as the definitive test. Five application rates were used. There was also a concurrent control group. The study groups were as follows:



Groups	Rates of the test item (L/ha)	Rates of Glyphosate* (g/ha)
Control group	0.0	0.0
Test item group I	1.5	827
Test item group II	3	1653
Test item group III	6	3306
Test item group IV	12	6612
Test item group V	24	13224

\*: based on the Glyphosate content in the test item, i.e. 551g/l provided by the Sponsor

Seeds of the test plant species were sown in plastic pots. The number of seeds per pot as well as the total number of seeds per application rate were 3 seeds/pot, i.e. 21 seeds/application rate (7 pots/application rate) for soybean, com, onion, oats, radish and tomato. The number of seeds per pot selection provided the adequate growth conditions and avoided overcrowding of plants during the experiment.

The test item was sprayed onto the soil surface. The experiment was conducted in a plant growth chamber with suitable environmental conditions for each test species were provided. The experiment was finished 14 days after the emergence of 50% of the control seedlings. During the experiment, the plants were observed for emergence on every day and visual phytotoxicity (7 and 14 days after the emergence of 50% of the control seedlings). At the end of the experiment, the number of plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60°C to a constant weight and weighed.

The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ERio, ER25, and ER50 and NOER values.

### Results

The test item, i.e. **Glyphosate 54% SL** applied at rates ranging from 1.5 to 24 L/ha had a varied impact on seedling emergence and seedling growth of all the plant species tested. The impact depended on the rate of the test item and species used. After the application of the test item 6 to 24L/ha, seedling emergence was delayed for all the species. After the application of the test item, seedling emergence was delayed for all the species including soybean, com, onion, oats, radish and tomato in comparison with the control. However, all the plant species tested emerged after the application of the test item at rates ranging from 1.5 to 24 L/ha. The phytotoxic symptoms for all the plant species tested were observed at all the rates of the test item used on day 14 after the emergence of 50% of the control seedlings. There was phytotoxic symptoms were observed for all the six plant species. The following phytotoxic symptoms were observed:

- Soybean, onion, oats: chlorosis, wilting, leaf deformation or stem deformation,
- Com, radish and tomato: chlorosis, necrosis, leaf deformation or stem deformation.

The endpoint values showing the impact of the test item on seedling emergence and seedling growth of the plant species tested are presented in Table given below.

GROWTH TEST

**Table 9. Soybean (*Glycine max*) – plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
1.5	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
3	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
6	R1	5	3.57	N, C	10	5.71	N, C
	R2	0			0		
	R3	10			15		
	R4	0			0		
	R5	10			15		
	R6	0			0		
	R7	0			0		
12	R1	10	9	C, Ld	15	14	C, Ld, Sd
	R2	15			20		
	R3	5			10		
	R4	_*			_*		
	R5	10			15		
	R6	_*			_*		
	R7	5			10		
24	R1	_*	23.33	C, Ld, Sd	_*	28.33	C, Ld, Sd, W
	R2	_*			_*		
	R3	25			30		
	R4	20			25		
	R5	_*			_*		
	R6	_*			_*		
	R7	25			30		

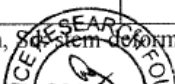
N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne: Necrosis, W-Wilting  
\*: lack of plants

**Table 14. Corn (*Zea mays*)—plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
1.5	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
3	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
6	R1	0	2.85	N, C	5	6.43	N, C, Ld
	R2	0			0		
	R3	10			15		
	R4	0			0		
	R5	0			5		
	R6	10			20		
	R7	0			0		
12	R1	10	8.33	N, C, Ld	15	13.33	C, Ld, Sd
	R2	—*			—*		
	R3	15			20		
	R4	0			5		
	R5	15			20		
	R6	10			15		
	R7	0			5		
24	R1	10	15	C, Ld, Sd	15	20	C, Ld, Sd, Ne
	R2	—*			—*		
	R3	20			25		
	R4	—*			—*		
	R5	10			15		
	R6	20			25		
	R7	—*			—*		

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne: Necrosis, W: Wilting

\*: lack of plants



**Table 19. Onion (*Allium cepa*) –plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
1.5	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
3	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
6	R1	10	4.29	N, C	15	7.14	N, C, Ld
	R2	0			0		
	R3	0			0		
	R4	5			10		
	R5	10			15		
	R6	5			10		
	R7	0			0		
12	R1	15	12.02	N, C	20	16.67	C, Ld
	R2	10			15		
	R3	_*			_*		
	R4	15			20		
	R5	0			10		
	R6	10			15		
	R7	15			20		
24	R1	_*	20	C, Ld, Sd	_*	25	C, Ld, Sd, W
	R2	_*			_*		
	R3	15			20		
	R4	20			25		
	R5	25			30		
	R6	20			25		
	R7	_*			_*		

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne: Necrosis, W- Wilting

\_: lack of plants

**Table 24. Oats (*Avena sativa*)– plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
1.5	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
3	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
6	R1	5	3.57	N, C	10	7.14	C, Ld
	R2	5			10		
	R3	0			5		
	R4	0			0		
	R5	10			15		
	R6	5			10		
	R7	0			0		
12	R1	10	10	C	15	15	C, Ld
	R2	15			20		
	R3	10			15		
	R4	10			15		
	R5	_*			_*		
	R6	5			10		
	R7	10			15		
24	R1	20	23.33	C, Ld, Sd	25	30	C, Ld, Sd, W
	R2	_*			_*		
	R3	_*			_*		
	R4	25			30		
	R5	_*			_*		
	R6	25			35		
	R7	_*			_*		

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne: Necrosis, W-Wilting

\_\*: lack of plants

**Table 29. Radish (*Raphanus sativus*) – plant damage.**

Application rateL/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
1.5	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
3	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
6	R1	0	5	N, C	0	8.57	N, C, Ld
	R2	10			15		
	R3	5			10		
	R4	10			15		
	R5	0			5		
	R6	0			0		
	R7	10			15		
12	R1	10	11	C	15	16	C, Ld
	R2	15			20		
	R3	5			10		
	R4	_*			_*		
	R5	10			15		
	R6	15			20		
	R7	_*			_*		
24	R1	_*	21.67	C, Ld, Sd	_*	30	C, Ld, Sd, Ne
	R2	25			30		
	R3	_*			_*		
	R4	20			25		
	R5	_*			_*		
	R6	_*			_*		
	R7	20			35		

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne: Necrosis, W-Wilting

\_: lack of plants

**Table 34. Tomato (*Solanum lycopersicon*)– plant damage.**

Application rate L/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
1.5	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
3	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
6	R1	0	4.28	N, C	0	7.86	N, C
	R2	0			5		
	R3	5			10		
	R4	10			15		
	R5	0			0		
	R6	10			15		
	R7	5			10		
12	R1	15	8.57	N,C	20	13.57	C, Ld
	R2	10			15		
	R3	0			5		
	R4	5			10		
	R5	10			15		
	R6	15			20		
	R7	5			10		
24	R1	25	18.33	C, Ld	30	23.33	C, Ld, Sd, Ne
	R2	_*			_*		
	R3	15			25		
	R4	_*			_*		
	R5	_*			_*		
	R6	15			30		
	R7	_*			_*		

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne: Necrosis, W: Wilting

\_\*: lack of plants

**Table 35. Endpoint values - the impact of the test item on seedling emergence and seedling growth of the plants tested.**

Endpoint value with 95% CL		Soybean ( <i>Glycine max</i> )	Corn ( <i>Zea mays</i> )	Onion ( <i>Allium cepa</i> )	Oats ( <i>Avena sativa</i> )	Radish ( <i>Raphanus sativus</i> )	Tomato ( <i>Solanum lycopersicon</i> )
Plant number at the end of the experiment							
ERio	L/ha <sup>a</sup>	1.53 (1.33- 1.73)	1.77 (1.55-1.99)	1.45 (1.24-1.66)	1.58 (1.37-1.79)	2.01 (1.78-2.24)	1.74 (1.52-1.96)
	L/ha <sup>b</sup>	843.0 (732.8 -953.2)	975.3 (854.1 - 1096.5)	799.0 (683.2-914.7)	870.6 (754.9-986.3)	1107.5 (980.8-1234.2)	958.7 (837.5-1080.0)
ER25	L/ha <sup>a</sup>	3.01 (2.73 - 3.29)	3.44 (3.14-3.74)	2.99 (2.70-3.28)	3.17 (2.88-3.46)	3.65 (3.36-3.94)	3.39 (3.09-3.69)
	L/ha <sup>b</sup>	1658.5 (1504.2 -1812.8)	1895.4 (1703.1-2060.7)	1647.5 (1487.7-1807.3)	1746.7 (1586.9-1906.5)	2011.2 (1851.4-2170.9)	1867.9 (1702.6-2033.2)
ER50	L/ha <sup>a</sup>	6.37 (5.92 -6.82)	7.18 (6.67-7.69)	6.68 (6.18-7.18)	6.84 (6.34-7.34)	7.09 (6.63-7.55)	7.11 (6.61-7.61)
	L/ha <sup>b</sup>	3509.9 (3261.9-3757.8)	3956.2 (3675.2-4237.2)	3680.7 (3405.2-3956.2)	3768.8 (3493.3-4044.3)	3906.6 (3653.1-4160.1)	3917.6 (3642.1-4193.1)
NOER	L/ha <sup>a</sup>	3.00	3.00	3.00	1.50	3.00	3.00
	L/ha <sup>b</sup>	1653.0	1653.0	1653.0	826.5	1653.0	1653.0





**Shoot length (plants without roots)**

<b>ERio</b>	' L/ha <sup>a</sup>	<b>1.87</b> <b>(1.65-2.09)</b>	<b>2.01</b> <b>(1.78-2.24)</b>	<b>1.63</b> <b>(1.41-1.85)</b>	<b>1.93</b> <b>(1.70-2.16)</b>	<b>1.66</b> <b>(1.44-1.88)</b>	<b>1.52</b> <b>(1.30-1.74)</b>
	L/ha <sup>b</sup>	<b>1030.4</b> <b>(909.2-1151.6)</b>	<b>1107.5</b> <b>(980.8-1234.2)</b>	<b>898.1</b> <b>(776.9-1019.4)</b>	<b>1063.4</b> <b>(936.7-1190.2)</b>	<b>914.7</b> <b>(793.4-1035.9)</b>	<b>837.5</b> <b>(716.3-958.7)</b>
<b>ER25</b>	L/ha <sup>a</sup>	<b>3.52</b> <b>(3.22-3.82)</b>	<b>3.69</b> <b>(3.39-3.99)</b>	<b>3.30</b> <b>(2.99-3.61)</b>	<b>3.61</b> <b>(3.31-3.91)</b>	<b>3.31</b> <b>(3.01-3.61)</b>	<b>3.18</b> <b>(2.87-3.49)</b>
	L/ha <sup>b</sup>	<b>1939.5</b> <b>(1774.2-2104.8)</b>	<b>2033.2</b> <b>(1867.9-2198.5)</b>	<b>1818.3</b> <b>(1647.5-1989.1)</b>	<b>1989.1</b> <b>(1823.8-2154.4)</b>	<b>1823.8</b> <b>(1658.5-1989.1)</b>	<b>1752.2</b> <b>(1581.4-1923.0)</b>
<b>ER50</b>	L/ha <sup>a</sup>	<b>7.14</b> <b>(6.65-7.63)</b>	<b>7.26</b> <b>(6.78-7.74)</b>	<b>7.20</b> <b>(6.67-7.73)</b>	<b>7.22</b> <b>(6.73-7.71)</b>	<b>7.13</b> <b>(6.61-7.65)</b>	<b>7.18</b> <b>(6.63-7.73)</b>
	L/ha <sup>b</sup>	<b>3934.1</b> <b>(3664.2-4204.1)</b>	<b>4000.3</b> <b>(3735.8-4264.7)</b>	<b>3967.2</b> <b>(3675.2-4259.2)</b>	<b>3978.2</b> <b>(3708.2-4248.2)</b>	<b>3928.6</b> <b>(3642.1-4215.2)</b>	<b>3956.2</b> <b>(3653.1-4259.2)</b>
<b>NOER</b>	L/ha <sup>a</sup>	<b>1.50</b>	<b>1.50</b>	<b>1.50</b>	<b>1.50</b>	<b>1.50</b>	<b>1.50</b>
	L/ha <sup>b</sup>	<b>826.5</b>	<b>826.5</b>	<b>826.5</b>	<b>826.5</b>	<b>826.5</b>	<b>826.5</b>

**Plant dry weight (plants without roots)**

<b>ERio</b>	<b>L/ha<sup>a</sup></b>	<b>1.75</b> <b>(1.53-1.97)</b>	<b>1.97</b> <b>(1.74-2.20)</b>	<b>1.64</b> <b>(1.42-1.86)</b>	<b>1.55</b> <b>(1.34-1.76)</b>	<b>1.67</b> <b>(1.45-1.89)</b>	<b>1.89</b> <b>(1.66-2.12)</b>
	<b>L/ha<sup>b</sup></b>	<b>964.3</b> <b>(843.0-1085.5)</b>	<b>1085.5</b> <b>(958.7-1212.2)</b>	<b>903.6</b> <b>(782.4-1024.9)</b>	<b>854.1</b> <b>(738.3-969.8)</b>	<b>920.2</b> <b>(799.0-1041.4)</b>	<b>1041.4</b> <b>(914.7-1168.1)</b>
<b>ER25</b>	<b>L/ha<sup>a</sup></b>	<b>3.39</b> <b>(3.09-3.69)</b>	<b>3.65</b> <b>(3.35-3.95)</b>	<b>3.24</b> <b>(2.95-3.53)</b>	<b>3.12</b> <b>(2.83-3.41)</b>	<b>3.35</b> <b>(3.04-3.66)</b>	<b>3.56</b> <b>(3.26-3.86)</b>
	<b>L/ha<sup>b</sup></b>	<b>1867.9</b> <b>(1702.6-2033.2)</b>	<b>2011.2</b> <b>(1845.9-2176.5)</b>	<b>1785.2</b> <b>(1625.5-1945.0)</b>	<b>1719.1</b> <b>(1559.3-1878.9)</b>	<b>1845.9</b> <b>(1675.0-2016.7)</b>	<b>1961.6</b> <b>(1796.3-2126.9)</b>
<b>ER50</b>	<b>L/ha<sup>a</sup></b>	<b>7.08</b> <b>(6.58-7.58)</b>	<b>7.24</b> <b>(6.75-7.73)</b>	<b>6.93</b> <b>(6.43-7.43)</b>	<b>6.79</b> <b>(6.29-7.29)</b>	<b>7.25</b> <b>(6.72-7.78)</b>	<b>7.17</b> <b>(6.72-7.62)</b>
	<b>L/ha<sup>b</sup></b>	<b>3901.1</b> <b>(3625.6-4176.6)</b>	<b>3989.2</b> <b>(3719.3-4259.2)</b>	<b>3818.4</b> <b>(3542.9-4093.)</b>	<b>3741.3</b> <b>(3465.8-4016.8)</b>	<b>3994.8</b> <b>(3702.7-4286.8)</b>	<b>3950.7</b> <b>(3702.7-4198.6)</b>
<b>NOER</b>	<b>L/ha<sup>a</sup></b>	<b>1.50</b>	<b>1.50</b>	<b>1.50</b>	<b>1.50</b>	<b>1.50</b>	<b>1.50</b>
	<b>L/ha<sup>b</sup></b>	<b>826.5</b>	<b>826.5</b>	<b>826.5</b>	<b>826.5</b>	<b>826.5</b>	<b>826.5</b>

**a:** value for the test item, i.e. Glyphosate 54% SL expressed as L/ha **b:** value for active substance, i.e Glyphosate expressed as g/ha

## 12. TEST VALIDITY CRITERIA

The following validity criteria were met:

- the seedling emergence in the control (validity criterion: at least 70%) was as follows:
  - 100% – Soybean,
  - 100% – Corn,
  - 100% – Onion,
  - 100% – Oats,
  - 100% – Radish,
  - 100% – Tomato,
- the mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%),
- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

## Results and Conclusions

The application of the test item at the rates ranging from 1.5 to 24 L/ha had a varied impact on seedling emergence and seedling growth of all the plant species tested.

After the application of the test item 6 to 24 L/ha, seedling emergence was delayed for all the species. However all the plant species emerged after the application of the test item at rates ranging from 1.5 to 24 L/ha. The phytotoxic symptoms were observed for all the plant species at all the rates on day 14 after the emergence of 50% of the control seedlings. The following symptoms were observed:

- Soybean, onion, oats: chlorosis, wilting, leaf deformation or stem deformation,
- Corn, radish and tomato: chlorosis, necrosis, leaf deformation or stem deformation.

**Table 5 - Endpoint values**

Endpoint Value (L/ha <sup>a</sup> )	Soybean ( <i>Glycine max</i> )	Corn ( <i>Zea mays</i> )	Onion ( <i>Allium cepa</i> )	Oats ( <i>Avena sativa</i> )	Radish ( <i>Raphanus sativus</i> )	Tomato ( <i>Solanum lycopersicon</i> )
<b>Plant number at the end of the experiment</b>						
<b>ER<sub>50</sub></b>	L/ha <sup>a</sup> 6.37 (5.92 – 6.82)	7.18 (6.67 – 7.69)	6.68 (6.18 – 7.18)	6.84 (6.34 – 7.34)	7.09 (6.63 – 7.55)	7.11 (6.61 – 7.61)
	g/ha <sup>b</sup> 3509.9 (3261.9 – 3757.8)	3956.2 (3675.2 – 4237.2)	3680.7 (3405.2 – 3956.2)	3768.8 (3493.3 – 4044.3)	3906.6 (3653.1 – 4160.1)	3917.6 (3642.1 – 4193.1)
<b>NOER</b>	L/ha <sup>a</sup> 3.00	3.00	3.00	1.50	3.00	3.00
	g/ha <sup>b</sup> 1653.0	1653.0	1653.0	826.5	1653.0	1653.0
<b>Shoot length (plants without roots)</b>						
<b>ER<sub>50</sub></b>	L/ha <sup>a</sup> 7.14 (6.65 – 7.63)	7.26 (6.78 – 7.74)	7.20 (6.67 – 7.73)	7.22 (6.73 – 7.71)	7.13 (6.61 – 7.65)	7.18 (6.63 – 7.73)
	g/ha <sup>b</sup> 3934.1 (3664.2 – 4204.1)	4000.3 (3735.8 – 4264.7)	3967.2 (3675.2 – 4259.2)	3978.2 (3708.2 – 4248.2)	3928.6 (3642.1 – 4215.2)	3956.2 (3653.1 – 4259.2)
<b>NOER</b>	L/ha <sup>a</sup> 1.50	1.50	1.50	1.50	1.50	1.50
	g/ha <sup>b</sup> 826.5	826.5	826.5	826.5	826.5	826.5
<b>Plant dry weight (plants without roots)</b>						
<b>ER<sub>50</sub></b>	L/ha <sup>a</sup> 7.08 (6.58 – 7.58)	7.24 (6.75 – 7.73)	6.93 (6.43 – 7.43)	6.79 (6.29 – 7.29)	7.25 (6.72 – 7.78)	7.17 (6.72 – 7.62)
	g/ha <sup>b</sup> 3901.1 (3625.6 – 4176.6)	3989.2 (3719.3 – 4259.2)	3818.4 (3542.9 – 4093)	3741.3 (3465.8 – 4016.8)	3994.8 (3702.7 – 4286.8)	3950.7 (3702.7 – 4198.6)
<b>NOER</b>	L/ha <sup>a</sup> 1.50	1.50	1.50	1.50	1.50	1.50
	g/ha <sup>b</sup> 826.5	826.5	826.5	826.5	826.5	826.5

a: value for the test item, i.e. Glyphosate 54% SL. Expressed as L/ha

b: value for the active substance, i.e. Glyphosate. Expressed as g/ha

**A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants**

**A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)**

**A 2.8 KCP 10.8 Monitoring data**