

# FINAL REGISTRATION REPORT

## Part B

### Section 6

#### Mammalian Toxicology

Detailed summary of the risk assessment

Product code: **ORKAN 350 SL/ SPRINTER 350 SL**

Chemical active substances:

Active substance 1, **MCPA**, 90 g/L

Active substance 2, **Glyphosate**, 260 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(renewal of authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

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## Version history

When	What
04/2020	Dossier submission date
09/2020	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR
11/2021	Supplement to the evaluation for non-professional uses

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## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on ORKAN 350 SL \***

Product name and code	ORKAN 350 SL/ SPRINTER 350 SL
Formulation type	Soluble concentrate [SL]
Active substance(s) (incl. content)	MCPA, 90 g/L Glyphosat, 260 g/L
Function	Herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

\* Information on the detailed composition of ORKAN 350 SL can be found in the confidential dRR Part C.

#### Justified proposals for classification and labelling

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

**Table 6.1-2: Justified proposals for classification and labelling for ORKAN 350 SL according to Regulation (EC) No 1272/2008**

Hazard class(es), categories	Eye Irrit 2
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H319 - Causes serious eye irritation.
Precautionary statement(s)	Prevention: P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection.  Response: P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 - If eye irritation persists: Get medical advice/attention.
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for ORKAN 350 SL**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	AOEM: Gloves and Work wear (arms, body and legs covered): M/L and A
Workers	Acceptable	German Model: Gloves and Work wear (arms, body and legs covered)

	Result	PPE / Risk mitigation measures
Residents	Acceptable	None
Bystanders	Acceptable	None

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

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

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

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

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks:  (e.g. safen- er/synergist (L/ha))  critical gap for operator, worker, resident or by- stander exposure based on AOEM, German model	Acceptability of exposure as- sessment			
			Method / Kind  (incl. applica- tion technique ***	Max. number (min. interval between applications)  a) per use b) per crop/ season	Max. application rate kg as/ha  a) a.s. 1 b) a.s. 2	Water L/ha  min / max			Operator	Worker	Residents	Bystander
	Pome fruits: Apple, Pear, Quince,Medlar, Loquat	F  Fn	Spraying, HCTM	1 ; -  I	5 – 8 L PPP/ha: a) 0.45 - 0.72 b) 1.3 - 2.08  50-70 mL/100m2	300	-	Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				
	Stone fruits: Cherry, Sweet cherry, Plum, Peach, Apricot, Nectarine	F  Fn	Spraying, HCTM	1 ; -  I	5 – 7 L PPP/ha: a) 0.45 – 0.63 b) 1.3 – 1.82  50-70 mL/100m2	300	-					
	Tree nuts: Hazelnuts, Walnuts	F	Spraying, HCTM	1 ; -	5 – 8 L PPP/ha: a) 0.45 - 0.72 b) 1.3 - 2.08	300	-					

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

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

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

Explanation for column 10 “Acceptability of exposure assessment”

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

### Data gaps

No data gaps

### Glyphosate:

- Relevance of all individual impurities present in the technical specification (except the two already identified relevant impurities, formaldehyde and N-Nitroso-glyphosate), in particular impu-

rities that elicited toxicological alerts according to QSAR assessments and the ones specified at higher level than the reference specification, in comparison with the toxicity profile of the parent compound.

- The full battery of Tier I screening assays according to the EDSP, or Level 2 and 3 tests currently indicated in the OECD Conceptual Framework, and analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors are needed to address the potential for endocrine-mediated mode of action regarding delay in preputial separation in F1 males and decrease in homogenisation resistant spermatids (*cauda epididymis*) observed in the most recent multigeneration study.

(EFSA Conclusion (EFSA Journal 2015;13(11):4302)

**MCPA:** No data gaps.

(Review report for the active substance MCPA, SANCO/4062/2001, (2008))

## 6.2 Toxicological Information on Active Substance(s)

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

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

	<b>MCPA</b>	<b>Glyphosate</b>
Common Name	MCPA	Glyphosate
CAS-No.	94-74-6	1071-83-6
<b>Classification and proposed labelling</b>		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	<p>Hazard classes (s), categories: Acute Tox. 4 - H302 Skin Irrit. 2 - H315 Eye Dam. 1 - H318</p> <p>Codes for hazard pictogram(s): GHS05, GHS07</p> <p>Signal word: Danger</p> <p>Hazard statement(s): H302 - Harmful if swallowed. H315 - Causes skin irritation. H318 - Causes serious eye damage. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects</p> <p>Precautionary statement(s): P102- Keep out of reach of children. P273- Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p>	<p>Hazard classes (s), categories: Eye Dam. 1 - H318</p> <p>Code(s) for hazard pictogram(s): GHS05</p> <p>Signal word: Danger</p> <p>Hazard statement(s): H318- Causes serious eye damage.</p> <p>Precautionary statement(s): P273- Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p>

	MCPA	Glyphosate
Additional C&L proposal	-	-
<b>Agreed EU endpoints</b>		
AOEL systemic	0.04 mg/kg bw/d	0.1 mg/kg bw/d (corrected for 20 % oral absorption)
Reference	Review report for the active substance MCPA, SANCO/4062/2001, (2008)	Peer review of the pesticide risk assessment of the active substance glyphosate” ( <i>EFSA Journal</i> 2015; 13(11):4302)
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>		
According to Review Report/EFSA Conclusion for active substance	None	Personal protective equipment (PPE), such as gloves during mixing and loading operations have to be considered for hand-held applications to ensure that operator exposure does not exceed the AOEL.

Formulation does not contain any substances classified as:

- acute dermal toxicity,
- respiratory or skin sensitizer,
- germ cell mutagenic,
- cancerogenic,
- toxic on reproduction,
- toxic on specific target organs (single exposure, repeat exposure)
- aspiration hazard.

Thus according to points 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10 of Regulation (EC) 1272/2008 product ORKAN 350 SL does not need to be classified in above mentioned categories.

### 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for ORKAN 350 SL is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

**Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for ORKAN 350 SL**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat (OECD 420)	> 2000 mg/kg bw	Yes	None	xxxxxxxxxxxxxx
LD <sub>50</sub> dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	xxxxxxxxxxxxxxxxxx
LC <sub>50</sub> inhalation (calculation method)	Not submitted, not necessary. Justification presented in Appendix 2			
Skin irritation, model system <i>in vivo</i> (OECD 404)	Non-irritant	Yes	None	xxxxxxxxxxxxxxxxxx
Eye irritation, model	Irritant	Yes	<b>Eye Irrit. 2</b>	xxxxxxxxxxxxxxxxxx



system <i>in vivo</i> (OECD 405)			(H319 - Causes serious eye irritation)	
Skin sensitisation (calculation method)	Non- Sensitising	Yes	None	-
	Justification presented in Appendix 2			
Supplementary studies for combinations of plant protection products	No data – not required			

## 6.4 Toxicological Evaluation of Groundwater Metabolites

### Glyphosate

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required (PEC<sub>GW</sub> simulation).

### MCPA

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

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in ORKAN 350 SL are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in ORKAN 350 SL**

	MCPA		Glyphosate	
	Value	Reference	Value	Reference
<b>Concentrate</b>	10 % (Default)	Guidance on dermal absorption. <i>EFSA Journal</i> 2017;15(6):4873.	10 % (Default)	Guidance on dermal absorption. <i>EFSA Journal</i> 2017;15(6):4873.
<b>Dilution</b>	50% (Default)		50% (Default)	

### 6.5.1 Justification for proposed values - glyphosate

No data on dermal absorption for glyphosate in ORKAN 350 SL is available.

Justifications for default values according to Guidance on Dermal Absorption (*EFSA Journal* 2017; 15(6):4873) are presented in the following table.

Default values of dermal absorption for ORKAN 350 SL according to Guidance on Dermal Absorption (*EFSA Journal* 2017;15(6):4873) are 10% for concentrate and 50% for dilution. ORKAN 350 SL is water-based formulation.

Regarding to Guidance on Dermal Absorption (2017), a default dermal absorption value of:

- 10% may be applied for concentrated products that are water-based/dispersed formulation;
- 50% may be applied for (in use) dilutions water-based formulation.

Based on above, Applicant has proposed for ORKAN 350 SL a default dermal absorption value of 10% for the concentrate and 50% for the spray solution.

**Table 6.5-2: Default dermal absorption rates for glyphosate**

	Value	Justification for value	Acceptability of justification
Concentrate	10%	In the absence of any supporting dermal absorption data for ORKAN 350 SL, it is proposed a dermal absorption value of 10% for the concentrate and 50 % in-use dilution, based on Guidance on dermal absorption. <i>EFSA Journal</i> 2017; 15(6);4873.	Acceptable
Dilution	50%		Acceptable

## 6.5.2 Justification for proposed values - MCPA

No data on dermal absorption for MCPA in ORKAN 350 SL is available.

No data on dermal absorption for MCPA in ORKAN 350 SL is available.

Justifications for default values according to Guidance on Dermal Absorption (*EFSA Journal* 2017; 15(6):4873) are presented in the following table.

Default values of dermal absorption for ORKAN 350 SL according to Guidance on Dermal Absorption (*EFSA Journal* 2017;15(6):4873) are 10% for concentrate and 50% for dilution. ORKAN 350 SL is water-based formulation.

Regarding to Guidance on Dermal Absorption (2017), a default dermal absorption value of:

- 10% may be applied for concentrated products that are water-based/dispersed formulation;
- 50% may be applied for (in use) dilutions water-based formulation.

Based on above, Applicant has proposed for ORKAN 350 SL a default dermal absorption value of 10% for the concentrate and 50% for the spray solution.

**Table 6.5-3: Default dermal absorption rates for MCPA**

	Value	Justification for value	Acceptability of justification
Concentrate	10%	In the absence of any supporting dermal absorption data for ORKAN 350 SL, it is proposed a dermal absorption value of 10% for the concentrate and 50 % in-use dilution, based on Guidance on dermal absorption. <i>EFSA Journal</i> 2017; 15(6);4873.	Acceptable
Dilution	50%		Acceptable

## 6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	ORKAN 350 SL/ SPRINTER 350 SL	
Formulation type	SL	
Category	Herbicide	
Active substance(s) (incl. content)	MCPA 90 g/L	Glyphosate 260 g/L
AOEL systemic	0.04 mg/kg bw/d	0.1 mg/kg bw/d
Inhalation absorption	100 %	100 %
Oral absorption	100 %	100 %
Dermal absorption	Concentrate: 10 % Dilution: 50 % (Default)	Concentrate: 10 % Dilution: 50 % (Default)

### 6.6.1 Selection of critical use(s) and justification

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

### 6.6.2 Operator exposure (KCP 7.2.1)

#### 6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of ORKAN 350 SL according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

The dose of 8 L/ha for pome fruits application represents worst case scenario, hence calculation was performed for the dose of 8L/ha both for pome fruits and for stone fruits.

**Table 6.6-2: Exposure models for intended uses**

Critical uses	Pome fruits (max. 8 L/ kg product/ha) Stone fruits (max. 7 L/ kg product/ha) Tree nuts (max. 8 L/ kg product/ha)
1 <sup>st</sup> Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

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

		MCPA		Glyphosate	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of system-ic AOEL	Total absorbed dose (mg/kg/day)	% of system-ic AOEL
<b>Pome fruits, Stone fruits, Tree nuts</b>					
<b>High Crop, Tractor Mounted (HCTM)</b> <b>Tractor mounted boom spray, application outdoors to high crops</b>					
Application rate		0.72 kg a.s./ha		2.08 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg Upward spraying Early season – without leaves)	No PPE	0.3025	756.4 %	0.810	810.8 %
	Gloves and Work wear (arms, body and legs covered): A	0.0323	80.9 %	0.0739	74 %
	Gloves and Work wear (arms, body and legs covered): M/L and A	0.0088	<b>21.9 %</b>	0.0243	<b>24.3 %</b>
<b>High Crop, Hand Held (HCHH)</b>					

<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg Upward spraying Early season – without leaves)	No PPE	0.6954	1738.7 %	0.926	925.8 %
	Gloves and Work wear (arms, body and legs covered) M/L and A	0.01475	<b>36.9 %</b>	0.0219	<b>21.9 %</b>

Operator exposure estimates carried out indicated that the acceptable **professional** operator exposure level (AOEL) will not be exceeded under the conditions of intended use provided that the operator is equipped with personal protective equipment (PPE) : Gloves and Work wear (arms, body and legs covered) M / L and A at application outdoors to high crops by Tractor Mounted (HCTM) and High Crop, Hand Held (HCHH)

Estimating the exposure for a professional operator allows to conclude that the application of the product in accordance with the label does not pose a health risk to non-professional users, provided that nitrile gloves are worn.

#### 6.6.2.2 Measurement of operator exposure

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

#### 6.6.3 Worker exposure (KCP 7.2.3)

##### 6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with ORKAN 350 SL according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

**Table 6.6-4: Exposure models for intended uses**

Critical uses	Pome fruits (max. 8 L/ kg product/ha) Stone fruits (max. 7 L/ kg product/ha) Tree nuts (max. 8 L/ kg product/ha)
Model	German re-entry model, Krebs et al. (2000)

**Table 6.6-5: Estimated worker exposure**

		MCPA		Glyphosate	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Number of applications and application rate		1 x 0.72 kg a.s./ha		1 x 2.08 kg a.s./ha	
High Crop, Tractor Mounted (HCTM)					

High Crop, Hand Held (HCHH)					
<b>German re-entry model</b> 8 hours/day <sup>(1)</sup> , DFR: 1 µg/cm <sup>2</sup> /kg a.s./ha TC: 4500 cm <sup>2</sup> /person/h <sup>(2)</sup> Body weight: 70 kg	no PPE <sup>(3)</sup>	0.1851	462.9 %	0.5349	534.9
	with PPE <sup>(4)</sup>	0.00926	<b>23.1 %</b>	0.0267	<b>26.7 %</b>

- (1) e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc. or 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.  
 (2) e.g. EUROPOEM II, 2002, Post-Application Exposure of Workers to Pesticides in Agriculture or US-EPA policy paper [EPA, Science Advisory Council for Exposure; Agricultural Transfer Coefficients, Policy # 3.]. TC: Transfer coefficient  
 (3) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves  
 (4) with PPE: clothing covering the arms, body and legs

There is no unacceptable risk for the worker wearing adequate work wear (arms, body and legs covered) (with PPE), when re-entering crops treated with ORKAN 350 SL.

It should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

**Assessment of exposure of a worker entering the area previously treated or handling a crop treated with ORKAN 350 SL is acceptable under the condition of using PPE: clothing covering the arms, body and legs after application of the proposed crop by Tractor Mounted (HCTM) and High Crop, Hand Held (HCHH)**

#### 6.6.3.2 Refinement of generic DFR value (KCP 7.2)

#### 6.6.3.3 Measurement of worker exposure

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

#### 6.6.4 Resident and bystander exposure (KCP 7.2.2)

##### 6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-6 shows the exposure model used for estimation of resident and bystander exposure to glyphosate and MCPA. The outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3.

Estimation of bystander and resident exposure during/ after application in high crops, using tractor-mounted boom spraying represent worst case scenario, compared to hand-held application, hence the calculation is present only for tractor mounted applicant.

**Table 6.6-6: Exposure models for intended uses**

Critical uses	Pome fruits (max. 8 L/ kg product/ha) Stone fruits (max. 7 L/ kg product/ha) Tree nuts (max. 8 L/ kg product/ha)
Model	Martin S. et al. (2008) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76.

**Table 6.6-7: Estimated resident exposure (longer term exposure)**

	MCPA		Glyphosate	
Model data	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Application rate:	1 x 0.72 kg a.s./ha		1 x 2.08 kg a.s./ha	
Tractor mounted, outdoor application to high crop Hand-held sprayer, outdoor application to high crop				
Bystanders (adult) Drift rate: 2.67 % (10 m) Body weight: 60 kg	0.0160	40.1 %	0.0464	46.4 %
Bystanders (children) Drift rate: 2.67 % (10 m) Body weight: 16.15 kg	0.0125	31.4 %	0.0363	36.3 %
Residents (adult) Drift rate: 2.67 % (10 m) Body weight: 60 kg	0.00117	2.9 %	0.00338	3.4 %
Residents (children) Drift rate: 2.67 % (10 m) Body weight: 16.15 kg	0.001185	4.6 %	0.0053	5.3 %

**There is no an unacceptable health risk to the public based on estimations of bystander and resident exposure (adults and children) for ORKAN 350 SL, using the critical uses.**

#### 6.6.4.2 Measurement of resident and/or bystander exposure

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

## 6.6.5 Combined exposure

The product is a mixture of two active substances.

### 6.6.5.1 Exposure assessment of glyphosate and MCPA in ORKAN 350 SL

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from **Błąd! Nie można odnaleźć źródła odwołania.**, 6.6-5 and 6.6-7. converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

**Table 6.6-8: Risk assessment from combined exposure**

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – AOEM, tractor mounted, Fruit crops, With PPE	glyphosate	0.24
	MCPA	0.22
	<b>Cumulative risk operators (HI)</b>	<b>0.46</b>
Operators – German model, handheld application, Fruit crops, With PPE	glyphosate	0.22
	MCPA	0.37
	<b>Cumulative risk workers (HI)</b>	<b>0.59</b>
Workers – AOEM, tractor mounted and handheld application, Fruit crops, With PPE (Work wear)	glyphosate	0.27
	MCPA	0.23
	<b>Cumulative risk workers (HI)</b>	<b>0.50</b>
Bystander - adult tractor mounted, handheld application, Fruit crops	glyphosate	0.46
	MCPA	0.40
	<b>Cumulative risk workers (HI)</b>	<b>0.86</b>
Bystander – child tractor mounted, handheld application, Fruit crops	glyphosate	0.36
	MCPA	0.31
	<b>Cumulative risk workers (HI)</b>	<b>0.67</b>
Resident - adult tractor mounted, handheld application, Fruit crops	glyphosate	0.03
	MCPA	0.03
	<b>Cumulative risk workers (HI)</b>	<b>0.06</b>
Resident – child tractor mounted, handheld application, Fruit crops	glyphosate	0.05
	MCPA	0.05
	<b>Cumulative risk workers (HI)</b>	<b>0.10</b>

**The Hazard Index is < 1. Thus, combined exposure to all active substances in ORKAN 350**

**SL is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.**



## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### List of data submitted by the applicant and relied on, already evaluated at national level

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1.1	xxxxxxxxxxxxxxxxxx	2009	ORKAN 350 SL: Acute Oral Toxicity Study on Rats. Study code: PO-14/09. xxxxxxxxxxxxxxxxxx GLP Unpublished	Y	Synthos Agro Sp z.o.o
KCP 7.1.2	xxxxxxxxxxxxxxxxxx	2009	ORKAN 350 SL: Acute Dermal Toxicity Study on Rats. Study code: DER-8/09 xxxxxxxxxxxxxxxxxx GLP Unpublished	Y	Synthos Agro Sp z.o.o
KCP 7.1.4	xxxxxxxxxxxxxxxxxx	2009	ORKAN 350 SL: Acute Skin Irritation/Corrosion Study on Rabbits. Study code: DDR-10/09. xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP Unpublished	Y	Synthos Agro Sp z.o.o
KCP 7.1.5	xxxxxxxxxxxxxxxxxx.	2009	ORKAN 350 SL: Acute eye irritation/corrosion study on rabbits. Study code: ODR-10/09 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP Unpublished	Y	Synthos Agro Sp z.o.o

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>

**List of data relied on not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>

## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

Comments of zRMS:	N/A
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### A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p><b>The study is acceptable</b></p> <p><b>Under the experimental conditions, the oral LD<sub>50</sub> of ORKAN 350 SL is higher than 2000 mg/kg bw in rats.</b></p> <p><b>No classification is required according to Regulation (EC) No. 1272/2008.</b></p>
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Reference:	KCP 7.1.1
Report	ORKAN 350 SL: Acute Oral Toxicity Study on Rats. xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx., 2009. Study code: PO-14/09.
Guideline(s):	OECD Guideline No. 420 (2001) / EU Method B.1.BIS.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Previously evaluated:	Yes, in 2012

#### Materials and methods

Test material (Lot/Batch No.)	ORKAN 350 SL (Batch No. 2)
Species	Rats, Wistar
No. of animals (group size)	5 rats/female
Dose(s)	2000 mg/kg bw
Once by metal stomach tube	Once by metal stomach tube
Vehicle/Dilution	Distilled water
Post exposure observation period	14 days
Remarks	None

#### Results and discussions

**Table A 1: Results of acute oral toxicity study in rats of ORKAN 350 SL**

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD <sub>50</sub> (mg/kg bw) (14 days)
Female rats				

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

<b>Mortality:</b>	No mortality occurred.
<b>Clinical signs:</b>	Yes. One rat: transient noises breathing (a symptom not related to the administration of the test material). The remaining females had no symptoms of toxicity.
<b>Body weight:</b>	During the 14-day experiment, body weights of all animals increased.
<b>Macroscopic examination:</b>	The necropsies performed at the end of the study revealed no apparent findings.

Under the experimental conditions, the oral LD<sub>50</sub> of ORKAN 350 SL is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	<p><b>The study is acceptable</b></p> <p><b>Under the experimental conditions, the dermal LD<sub>50</sub> of ORKAN 350 SL is higher than 2000 mg/kg bw in rats.</b></p> <p><b>No classification is required according to Regulation (EC) No. 1272/2008.</b></p>
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Reference:	KCP 7.1.2
Report	ORKAN 350 SL: Acute Dermal Toxicity Study on Rats. xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx 2009. Study code: DER-8/09.
Guideline(s):	OECD Guideline No. 402 (1987) / EU Method B.3.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Previously evaluated:	Yes, in 2012

<b>Test material (Lot/Batch No.)</b>	ORKAN 350 SL (Batch No. 2)
<b>Species</b>	Rat, Wistar
<b>No. of animals (group size)</b>	10 rats (5 male and 5 female)
<b>Dose(s)</b>	2000 mg/kg bw

<b>Exposure</b>	24 hours (dermal)
<b>Vehicle/Dilution</b>	None
<b>Post exposure observation period</b>	14 days
<b>Remarks</b>	None

## Results and discussions

**Table A 3: Results of acute dermal toxicity study in rats of ORKAN 350 SL**

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD <sub>50</sub> (mg/kg bw) (14 days)
Male rats				
2000	0/1/5	1 <sup>st</sup> day	-	> 2000
Female rats				
2000	0/5/5	1 <sup>st</sup> – 3 <sup>rd</sup> day to 4 <sup>th</sup> - 8 <sup>th</sup> day	-	> 2000

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

**Table A 4: Summary of findings of acute dermal toxicity study in rats of ORKAN 350 SL**

<b>Mortality:</b>	No mortality occurred.
<b>Clinical signs:</b>	Yes. One male: erythema. In all females: erythema and scabs. One female: ruffling hair.
<b>Body weight:</b>	During the 14-day experiment, body weights of all animals increased.
<b>Macroscopic examination:</b>	The necropsies performed at the end of the study revealed no apparent findings.

## Conclusion

Under the experimental conditions, the dermal LD<sub>50</sub> of ORKAN 350 SL is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

### A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	<p><b>Calculation method is acceptable</b></p> <p><b>ORKAN 350 SL does not contain any component which is classified as acute inhalation toxicity, therefore the product will not be classified as acute inhalation toxicity.</b></p> <p><b>Therefore, no classification is required.</b></p>
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No data on acute inhalation toxicity for glyphosate and MCPA in ORKAN 350 SL is available. The recommended way of spraying formulation ORKAN 350 SL results in production of medium drops size. ORKAN 350 SL contains active substances with a vapour pressure below  $1 \times 10^{-2}$  Pa (vapour pressure glyphosate:  $1.31 \times 10^{-5}$  Pa at 25 °C (98.6%) and vapour pressure MCPA:  $4 \times 10^{-4}$  Pa at 32 °C (99.4%)). ORKAN 350 SL will not be used as a fumigant or an aerosol.

### Calculation method (Regulation (EC) No 1272/2008)

## A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	<p><b>The study is acceptable</b></p> <p><b>Under the experimental conditions, ORKAN 350 SL is not a skin irritant.</b></p> <p><b>Thus, no classification is required according to Regulation (EC) No. 1272/2008.</b></p>
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### A 2.5.1 Study 1

Reference:	KCP 7.1.4
Report	ORKAN 350 SL: Acute Skin Irritation/Corrosion Study on Rabbits. xxx 2009. Study code: DDR-10/09.
Guideline(s):	OECD Guideline No. 404 (2002)/ EU Method B.4.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Previously evaluated:	Yes, in 2012

## Materials and methods

<b>Test material (Lot/Batch No.)</b>	ORKAN 350 SL (Batch No. 2)
<b>Species</b>	Rabbit, New Zealand White
<b>No. of animals (group size)</b>	3 (2 females, male)
<b>Initial test using one animal</b>	Yes
<b>Exposure</b>	0.5 mL (4 hours)
<b>Post exposure observation period</b>	7 days
<b>Remarks</b>	None

## Results and discussions

**Table A 5: Skin irritation of ORKAN 350 SL**

Animal No.		Scores after treatment *				7 day	Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h			
1	Erythema Oedema	1 0	1 0	1 0	0 0	- -	0.7 0	3 -
2	Erythema Oedema	1 0	2 1	2 1	2 0	0 0	2 0.7	- 3
3	Erythema	2	2	1	0	-	1	3

	Oedema	0	0	0	0	-	0	-
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\* scores in the range of 0 to 4

<b>Clinical signs:</b>	After 7 days, no general clinical changes were observed.
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## Conclusion

Under the experimental conditions, ORKAN 350 SL is **not a skin irritant**. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

## A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	<p><b>The study is acceptable</b></p> <p><b>Under the experimental conditions, ORKAN 350 SL is an eye irritant. Thus, classification is required according to Regulation (EC) No. 1272/2008: Eye Irrit.2/H319 (Causes serious eye irritation).</b></p>
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### A 2.6.1 Study 1

Reference:	KCP 7.1.5
Report	ORKAN 350 SL: Acute eye irritation/corrosion study on rabbits. xxxxxxxxxxxxxxxxxxxxxxxxx., 2009. Study code: ODR-10/09.
Guideline(s):	OECD Guideline No 405 (2002)/ EU Method B.5.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Previously evaluated:	Yes, in 2012

## Materials and methods

<b>Test material (Lot/Batch No.)</b>	ORKAN 350 SL (Batch No. 2)
<b>Species</b>	Rabbit, New Zealand White
<b>No. of animals (group size)</b>	2 males
<b>Initial test using one animal</b>	Yes
<b>Exposure</b>	0.1 mL (single instillation in conjunctival sac)
<b>Irrigation (time point)</b>	No
<b>Post exposure observation period</b>	14 days
<b>Remarks</b>	None

## Results and discussions

**Table A 6: Eye irritation of ORKAN 350 SL**

Animal No.		Scores after treatment *						Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h	7 days	14 days		
1	Corneal opacity	1	2	2	2	0	0	2	-
	Iritis	0	1	1	1	0	0	1	-
	Redness conjunctivae	2	2	2	1	1	0	1.7	-
	Chemosis conjunctivae	2	2	3	2	0	0	2.3	-
2	Corneal opacity	1	1	1	1	0	0	1	-
	Iritis	0	0	0	0	0	0	0	-
	Redness conjunctivae	2	3	3	3	1	0	3	-
	Chemosis conjunctivae	2	2	1	1	0	0	1.3	-

\* scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

<b>Clinical signs:</b>	After 14 days, no general clinical changes were observed.
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This Test Guideline (adopted in 1981 and updated in 1987, 2002, 2012 and 2017) includes the recommendation that prior to undertaking the described *in vivo* test for acute eye irritation/corrosion, a weight-of-the-evidence analysis be performed on the existing relevant data. The update in 2012 mainly focused on the use of analgesics and anesthetics without impacting the basic concept and structure of the Test Guideline. In 2017 OECD Guideline for the Testing of Chemicals No. 405 was updated, but the methodology of the test was not changed.

## Conclusion

Under the experimental conditions, ORKAN 350 SL is **an eye irritant**. Thus, classification is required according to Regulation (EC) No. 1272/2008: **H319** (Causes serious eye irritation).

## A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<b>Calculation method</b>  <b>ORKAN 350 SL does not contain any component which is classified as skin sensitizer with hazard statement H317, therefore the product will not be classified as skin sensitizer.</b>
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## Calculation method (Regulation (EC) No 1272/2008)

ORKAN 350 SL does not contain any component which is classified as respiratory sensitizer with hazard statement H334, therefore the product will not be classified as respiratory sensitizer with hazard statement H334.

ORKAN 350 SL does not contain any component which is classified as skin sensitizer with hazard statement H317, therefore the product will not be classified as skin sensitizer with hazard statement H317.



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

## **A 2.9                    Data on co-formulants (KCP 7.4)**

### **A 2.9.1                Material safety data sheet for each co-formulant**

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

### **A 2.9.2                Available toxicological data for each co-formulant**

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

### **A 2.10                Studies on dermal absorption (KCP 7.3)**

According requirements from Reg. No. 284/2013/WE the study shall be conducted when dermal exposure is a significant exposure route and no acceptable risk is estimated using default absorption value.

Use of plant protection product ORKAN 350 SL is safe for operator, taking into account proposed dose of product, type of usage, type of personal protective equipment (gloves, protective garment and sturdy footwear). Using tractor mounted boom sprayer, hand-held sprayer and maintain general rules of safety and hygiene of working with plant protection products and comply with requirements enclosed in label, risk during employ ORKAN 350 SL is acceptable, absorbed dose of glyphosate and MCPA has safe value, below AOEL for these active ingredients.

According to above there isn't necessity to do tests of dermal absorption for ORKAN 350 SL.

**Acceptable**

### **A 2.11                Other/Special Studies**

## Appendix 3 Exposure calculations

### A 3.1 Operator exposure calculations (KCP 7.2.1.1)

#### A 3.1.1 Calculations for glyphosate

##### High Crop, Tractor Mounted (HCTM)

**Table A 7: Input parameters considered for the estimation of operator exposure**

Formulation type	SL		Crop type	Pome ad stone fruits, Tree nuts
Application rate (AR)	2.08	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	50	% (dilution)	Closed cabin	Yes
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.1	mg/kg bw/d	Water soluble bag	No

##### High Crop, Hand Held (HCHH)

**Table A 8: Input parameters considered for the estimation of operator exposure**

Formulation type	SL		Crop type	Pome ad stone fruits, Tree nuts
Application rate (AR)	2.08	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	4	ha	Application equipment	Manual-hand held
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	50	% (dilution)	Closed cabin	Yes
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.1	mg/kg bw/d	Water soluble bag	No

**Table A 9: Estimation of acute operator exposure towards active substance- glyphosate according to EFSA guidance – Vehicle mounted boom sprayer**

**Operator exposure for ORKAN 350 SL outdoor spray applications**

Application rate of active substance	2,08 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	10 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	20,8 kg a.s./day	<i>i_AmoutAS</i>
Dermal absorption of the product	10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Season	late (dense foliage)	
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Upward sprayingVehicle-mounted		

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	50239	189082	AOEM	
	Body	30119	173943	AOEM	
	Head	1079	5919	AOEM	
	Protected hands (gloves)	248	4120	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	350	3042	AOEM	
	Protected head (hood and face shield)	17	335	AOEM	
	Inhalation	9	31	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
Application	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	19493	43172	AOEM	No data available for a drift reduction scenario
	Body	61082	173757	AOEM	
	Head	311	4044	AOEM	
	Protected hands (gloves)	732	15863	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1415	3345	AOEM	
	Inhalation	54	435	AOEM	
Application	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	Yes		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	48,6502226	1,4599119
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,8108370	0,0243319
% of RVNAS	810,84%	24,33%

**Table A 10: Estimation of acute operator exposure towards active substance- glyphosate according to EFSA guidance – Manual-hand held sprayer**

**Operator exposure for ORKAN 350 SL outdoor spray applications**

Application rate of active substance	2,08 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	4 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	8,32 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Season	early (without leaves)	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	24814	92639	AOEM	
	Body	15817	133289	AOEM	
	Head	432	2368	AOEM	
	Protected hands (gloves)	137	1648	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	155	1217	AOEM	
	Protected head (hood and face shield)	7	134	AOEM	
	Inhalation	7	30	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	16002	44503	AOEM	No data available for a drift reduction scenario
	Body	85630	182328	AOEM	
	Head	301	1645	AOEM	
	Protected hands (gloves)	199	1033	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	469	645	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	Yes		vehicle mounted upward spraying only	

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	55,5486769	1,3146716
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,9258113	0,0219112
% of RVNAS	925,81%	21,91%

### A 3.1.2 Calculations for MCPA

#### High Crop, Tractor Mounted (HCTM)

**Table A 11: Input parameters considered for the estimation of operator exposure**

Formulation type	SL		Crop type	Pome ad stone fruits, Tree nuts
Application rate (AR)	0.72	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	50	% (dilution)	Closed cabin	Yes
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.04	mg/kg bw/d	Water soluble bag	No

#### High Crop, Hand Held (HCHH)

**Table A 12: Input parameters considered for the estimation of operator exposure**

Formulation type	SL		Crop type	Pome ad stone fruits, Tree nuts
Application rate (AR)	0.72	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	4	ha	Application equipment	Manual-hand held
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	50	% (dilution)	Closed cabin	Yes
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.04	mg/kg bw/d	Water soluble bag	No

**Table A 13: Estimation of acute operator exposure towards active substance- MCPA according to EFSA guidance – Vehicle-mounted boom sprayer**

**Operator exposure for ORKAN 350 SL outdoor spray applications**

Application rate of active substance	0,72 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	10 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	7,2 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Season	late (dense foliage)	
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Upward sprayingVehicle-mounted		

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	22200	82774	AOEM	
	Body	14288	127807	AOEM	
	Head	374	2049	AOEM	
	Protected hands (gloves)	124	1426	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	137	1053	AOEM	
	Protected head (hood and face shield)	6	116	AOEM	
	Inhalation	7	30	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
Application	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	7609	14944	AOEM	No data available for a drift reduction scenario
	Body	21144	60147	AOEM	
	Head	108	1400	AOEM	
	Protected hands (gloves)	253	5491	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	490	1158	AOEM	
	Inhalation	30	151	AOEM	
Application	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	Yes		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	18,1528109	0,5252735
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,3025468	0,0087546
% of RVNAS	756,37%	21,89%

**Table A 14: Estimation of acute operator exposure towards active substance- MCPA according to EFSA guidance – Manual-hand held sprayer**

**Operator exposure for ORKAN 350 SL outdoor spray applications**

Application rate of active substance	0,72 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	4 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	2,88 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Season	early (without leaves)	
	OutdoorSoluble concentrates, emulsifiable concentrate, etc. Upward sprayingManual-Hand held	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	10965	40555	AOEM	
	Body	7503	97936	AOEM	
	Head	149	820	AOEM	
	Protected hands (gloves)	69	570	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	61	421	AOEM	
	Protected head (hood and face shield)	2	46	AOEM	
	Inhalation	5	29	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

  

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	6590	19766	AOEM	No data available for a drift reduction scenario
	Body	72529	180526	AOEM	
	Head	214	1162	AOEM	
	Protected hands (gloves)	69	358	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	194	343	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	Yes		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	41,7277033	0,8851087
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,6954617	0,0147518
% of RVNAS	1738,65%	36,88%

### A 3.2 Worker exposure calculations (KCP 7.2.3.1)

#### A 3.2.1 Calculations for glyphosate

**Table A 15: Input parameters considered for the estimation of worker exposure**

<b>Intended use(s):</b>	Pome and stone fruit, Tree nuts	<b>Dislodgeable foliar residues (DFR):</b>	1	µg/cm <sup>2</sup> /kg a.s.
<b>Application rate (AR):</b>	2,08 kg a.s./ha	<b>Transfer coefficient (TC):</b>	4500	cm <sup>2</sup> /person/h
<b>Number of applications (NA):</b>	1	<b>Work rate per day (WR):</b>	8	h/d
<b>Body weight (BW):</b>	70 kg/person	<b>PPE</b>	5	%
<b>Dermal absorption (DA):</b>	50 % ('worst case')			
<b>AOEL</b>	0,1 mg/kg bw/d			

**Table A 16: Estimation of worker exposure towards active substance-- glyphosate according to RE-ENTRY Model**

Worker exposure towards Glyphosat					
Without PPE <sup>1)</sup>			With PPE <sup>2)</sup>		
"Worker (re-entry): Systemic dermal exposure after application in Pome and stone fruits					
SDE <sub>w</sub> = (DFR x TC x WR x AR x NA x DA) / BW			SDE <sub>w</sub> = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 4500 x 8 x 2,08 x 1 x 50%) / 70			(1 x 4500 x 8 x 2,08 x 1 x 5% x 50%) / 70		
External dermal exposure	74,88	mg/person	External dermal exposure	3,74	mg/person
External dermal exposure	1,07	mg/kg bw/d	External dermal exposure	0,05	mg/kg bw/d
Total systemic exposure	37,44	mg/person	Total systemic exposure	1,87	mg/person
Total systemic exposure	0,534857	mg/kg bw/d	Total systemic exposure	0,026743	mg/kg bw/d
% of AOEL	534.9	%	% of AOEL	26.7	%

1) acceptable without PPE: allocation of BVL code SF245-01 for spray applications

2) acceptable only with PPE: allocation of BVL code SF1891 and SF190 for home and allotment garden applications, respectively (cf. Krebs et al., 2000)

#### A 3.2.2 Calculations for MCPA

**Table A 17: Input parameters considered for the estimation of worker exposure**

<b>Intended use(s):</b>	Pome and stone fruits, Tree nuts	<b>Dislodgeable foliar residues (DFR):</b>	1	µg/cm <sup>2</sup> /kg a.s.
<b>Application rate (AR):</b>	0,72 kg a.s./ha	<b>Transfer coefficient (TC):</b>	4500	cm <sup>2</sup> /person/h
<b>Number of applications (NA):</b>	1	<b>Work rate per day (WR):</b>	8	h/d
<b>Body weight (BW):</b>	70 kg/person	<b>PPE</b>	5	%
<b>Dermal absorption (DA):</b>	50 % ('worst case')			
<b>AOEL</b>	0,04 mg/kg bw/d			

**Table A 18: Estimation of worker exposure towards active substance-MCPA according to RE-ENTRY Model**

Worker exposure towards MCPA						
Without PPE <sup>1)</sup>				With PPE <sup>2)</sup>		
Worker (re-entry): Systemic dermal exposure after application in Pome and stone fruits						
SDE <sub>w</sub> = (DFR x TC x WR x AR x NA x DA) / BW				SDE <sub>w</sub> = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 4500 x 8 x 0,72 x 1 x 50%) / 70				(1 x 4500 x 8 x 0,72 x 1 x 5% x 50%) / 70		
External dermal exposure	25,92	mg/person		External dermal exposure	1,30	mg/person



External dermal exposure	0,37	mg/kg bw/d	External dermal exposure	0,02	mg/kg bw/d
Total systemic exposure	12,96	mg/person	Total systemic exposure	0,65	mg/person
<b>Total systemic exposure</b>	<b>0,185143</b>	<b>mg/kg bw/d</b>	<b>Total systemic exposure</b>	<b>0,009257</b>	<b>mg/kg bw/d</b>
<b>% of AOEL</b>	<b>462,9</b>	<b>%</b>	<b>% of AOEL</b>	<b>23,1</b>	<b>%</b>

- 1) acceptable without PPE: allocation of BVL code SF245-01 for spray applications  
2) acceptable only with PPE: allocation of BVL code SF1891 and SF190 for home and allotment garden applications, respectively (cf. Krebs et al., 2000)

### A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for glyphosate

**Table A 19: Input parameters considered for the estimation of bystander exposure**

<b>Intended use(s):</b>	Pome and stone fruits, Tree nuts		<b>Drift (D):</b>	2,67	% (HCHH, 10 m)
<b>Application rate (AR):</b>	2,08	kg a.s./ha	<b>Exposed Body Surface Area (BSA):</b>	1	m <sup>2</sup> (adults)
				0,21	m <sup>2</sup> (children)
<b>Body weight (BW):</b>	60	kg/person (adults)	<b>Specific Inhalation Exposure (I<sub>A</sub>):</b>	0,3	mg/kg a.s. (6 hours, adults)
	16,15	kg/person (children)		0,17241	mg/kg a.s. (6 hours, children)
<b>Dermal absorption (DA):</b>	50,00	% ('worst case')	<b>Area Treated (A):</b>	1	ha/d (based on High crops, hand held (HCHH))
<b>Inhalation absorption (IA):</b>	100	%	<b>Exposure duration (T):</b>	5	min
<b>AOEL:</b>	0,1	mg/kg bw/d			

**Table A 20: Estimation of bystander exposure towards glyphosate**

Adults			Children		
Bystander: Dermal exposure after application in Pome and stone fruits (via spray drift)					
SDE <sub>B</sub> = (AR x D x BSA x DA) / BW			SDE <sub>B</sub> = (AR x D x BSA x DA) / BW		
(208 x 2,67% x 1 x 50%) / 60			(208 x 2,67% x 0,21 x 50%) / 16,15		
External exposure	5,5536	mg/person	External exposure	1,166256	mg/person
External exposure	0,09256	mg/kg bw/d	External exposure	0,072214	mg/kg bw/d
Absorbed dose:	0,0462800	mg/kg bw/d	Absorbed dose:	0,0361070	mg/kg bw/d
Bystander: Inhalation exposure after application in Pome and stone fruits					
SIE <sub>B</sub> = (I* <sub>A</sub> x AR x A x T x IA) / BW			SIE <sub>B</sub> = (I* <sub>A</sub> x AR x A x T x IA) / BW		
(0,300 / 360 x 2,08 x 1 x 5 x 100%) / 60			(0,172 / 360 x 2,08 x 1 x 5 x 100%) / 16,15		
External exposure	0,0086667	mg/person	External exposure	0,0049808	mg/person
External exposure	0,0001444	mg/kg bw/d	External exposure	0,0003084	mg/kg bw/d
Absorbed dose:	0,0001444	mg/kg bw/d	Absorbed dose:	0,0003084	mg/kg bw/d
Total systemic exposure: SE <sub>B</sub> = SDE <sub>B</sub> + SIE <sub>B</sub>			Total systemic exposure: SE <sub>B</sub> = SDE <sub>B</sub> + SIE <sub>B</sub>		
Total systemic exposure (absorbed dose)	2,7854667	mg/person	Total systemic exposure (absorbed dose)	0,5881088	mg/person
Total systemic exposure (absorbed dose)	0,0464244	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0364154	mg/kg bw/d
% of AOEL:	46,42	%	% of AOEL:	36,42	%

**Table A 21: Input parameters considered for the estimation of resident exposure**

<b>Intended use(s):</b>	Pome and stone fruits, Tree nuts		<b>Drift (D):</b>	2,67	% (HCHH, 10 m)
<b>Application rate (AR):</b>	2,08	kg a.s./ha	<b>Transfer coefficient (TC):</b>	7300	cm <sup>2</sup> /h (adults)
				2600	cm <sup>2</sup> /h (children)
<b>Number of applications (NA):</b>	1		<b>Turf Transferable Residues (TTR):</b>	5	%
<b>Body weight (BW):</b>	60	kg/person (adults)	<b>Exposure Duration (H):</b>	2	h
	16,15	kg/person (children)	<b>Airborne Concentration of Vapour (ACV):</b>	none	
<b>Dermal absorption (DA):</b>	50,00	% ('worst case')	<b>Inhalation Rate (IR):</b>	16,57	m <sup>3</sup> /d (adults),
<b>Inhalation absorption (IA):</b>	100	%		8,31	m <sup>3</sup> /d (children)
<b>Oral absorption (OA)</b>	100	%	<b>Saliva Extraction Factor (SE):</b>	50	%
<b>AOEL</b>	0,1	mg/kg bw/d	<b>Surface Area of Hands (SA):</b>	20	cm <sup>2</sup>
			<b>Frequency of Hand to Mouth (Freq):</b>	20	events/h
			<b>Dislodgeable foliar residues (DFR):</b>	20	%
			<b>Ingestion Rate for Mouthing of Grass/Day (IgR):</b>	25	cm <sup>2</sup> /d

**Table A 22: Estimation of resident exposure towards**

Adults			Children		
Residents: Dermal exposure after application in Pome and stone fruits (via deposits caused by spray drift)					
SDE <sub>R</sub> = (AR x NA x D x TTR x TC x H x DA) / BW			SDE <sub>R</sub> = (AR x NA x D x TTR x TC x H x DA) / BW		
(0,0208 x 1 x 3,6% x 5% x 7300 x 2 x 50%) / 60			(0,0208 x 1 x 3,6% x 5% x 2600 x 2 x 50%) / 16,15		
External exposure	0,4054128	mg/person	External exposure	0,1443936	mg/person
External exposure	0,0067569	mg/kg bw/d	External exposure	0,0089408	mg/kg bw/d
Absorbed dose:	0,0033784	mg/kg bw/d	Absorbed dose:	0,0044704	mg/kg bw/d
Residents: Inhalation exposure to vapour					
SIE <sub>R</sub> = (AC <sub>V</sub> x IR x IA) / BW			SIE <sub>R</sub> = (AC <sub>V</sub> x IR x IA) / BW		
(0 x 16,57 x 100%) / 60			(0 x 8,31 x 100%) / 16,15		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		none	Absorbed dose:		none
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE <sub>H</sub> = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0,0208 x 1 x 3,6% x 5% x 50% x 20 x 20 x 2 x 100%) / 16,15		
			External exposure	0,0111072	mg/person
			External exposure	0,0006878	mg/kg bw/d
			Absorbed dose	0,0006878	mg/kg bw/d
			Residents: Oral exposure (object-to-mouth transfer)		

			$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$ FALSZ		
			External exposure	0,0027768	mg/person
			External exposure	0,0001719	mg/kg bw/d
			Absorbed dose	0,0001719	mg/kg bw/d
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$		
Total systemic exposure (absorbed dose)	0,2027064	mg/person	Total systemic exposure (absorbed dose)	0,0860808	mg/person
<b>Total systemic exposure (absorbed dose)</b>	<b>0,0033784</b>	<b>mg/kg bw/d</b>	<b>Total systemic exposure (absorbed dose)</b>	<b>0,0053301</b>	<b>mg/kg bw/d</b>
<b>% of AOEL:</b>	<b>3,38</b>	<b>%</b>	<b>% of AOEL:</b>	<b>5,33</b>	<b>%</b>

### A 3.3.2 Calculations for MCPA

**Table A 23: Input parameters considered for the estimation of bystander exposure**

<b>Intended use(s):</b>	Pome and stone fruits, Tree nuts		<b>Drift (D):</b>	2,67	% (HCTM, 10 m)
<b>Application rate (AR):</b>	0,72	kg a.s./ha	<b>Exposed Body Surface Area (BSA):</b>	1	m <sup>2</sup> (adults)
				0,21	m <sup>2</sup> (children)
<b>Body weight (BW):</b>	60	kg/person (adults)	<b>Specific Inhalation Exposure (I*<sub>A</sub>):</b>	0,018	mg/kg a.s. (6 hours, adults)
	16,15	kg/person (children)		0,01034	mg/kg a.s. (6 hours, children)
<b>Dermal absorption (DA):</b>	50,00	% ('worst case')	<b>Area Treated (A):</b>	8	ha/d (based on High crops, tractor mounted (HCTM))
<b>Inhalation absorption (IA):</b>	100	%	<b>Exposure duration (T):</b>	5	min
<b>AOEL:</b>	0,04	mg/kg bw/d			

**Table A 24: Estimation of bystander exposure towards MCPA**

Bystander exposure towards MCPA					
Adults			Children		
Bystander: Dermal exposure after application in Pome and stone fruits (via spray drift)					
SDE <sub>B</sub> = (AR x D x BSA x DA) / BW			SDE <sub>B</sub> = (AR x D x BSA x DA) / BW		
(72 x 2,67% x 1 x 50%) / 60			(72 x 2,67% x 0,21 x 50%) / 16,15		
External exposure	1,9224	mg/person	External exposure	0,403704	mg/person
External exposure	0,03204	mg/kg bw/d	External exposure	0,0249972	mg/kg bw/d
Absorbed dose:	0,0160200	mg/kg bw/d	Absorbed dose:	0,0124986	mg/kg bw/d
Bystander: Inhalation exposure after application in Pome and stone fruits					
SIE <sub>B</sub> = (I* <sub>A</sub> x AR x A x T x IA) / BW			SIE <sub>B</sub> = (I* <sub>A</sub> x AR x A x T x IA) / BW		
(0,018 / 360 x 0,72 x 8 x 5 x 100%) / 60			(0,010 / 360 x 0,72 x 8 x 5 x 100%) / 16,15		
External exposure	0,00144	mg/person	External exposure	0,0008276	mg/person
External exposure	0,000024	mg/kg bw/d	External exposure	5,124E-05	mg/kg bw/d
Absorbed dose:	0,0000240	mg/kg bw/d	Absorbed dose:	0,0000512	mg/kg bw/d
Total systemic exposure: SE <sub>B</sub> = SDE <sub>B</sub> + SIE <sub>B</sub>			Total systemic exposure: SE <sub>B</sub> = SDE <sub>B</sub> + SIE <sub>B</sub>		

Total systemic exposure (absorbed dose)	0,96264	mg/person	Total systemic exposure (absorbed dose)	0,2026796	mg/person
<b>Total systemic exposure (absorbed dose)</b>	<b>0,0160440</b>	<b>mg/kg bw/d</b>	<b>Total systemic exposure (absorbed dose)</b>	<b>0,0125498</b>	<b>mg/kg bw/d</b>
<b>% of AOEL:</b>	<b>40,11</b>	<b>%</b>	<b>% of AOEL:</b>	<b>31,37</b>	<b>%</b>

**Table A 25: Input parameters considered for the estimation of resident exposure**

<b>Intended use(s):</b>	Pome and stone fruits, Tree nuts		<b>Drift (D):</b>	2,67	% (HCTM, 10 m)
<b>Application rate (AR):</b>	0,72	kg a.s./ha	<b>Transfer coefficient (TC):</b>	7300	cm <sup>2</sup> /h (adults)
				2600	cm <sup>2</sup> /h (children)
<b>Number of applications (NA):</b>	1		<b>Turf Transferable Residues (TTR):</b>	5	%
<b>Body weight (BW):</b>	60	kg/person (adults)	<b>Exposure Duration (H):</b>	2	h
	16,15	kg/person (children)	<b>Airborne Concentration of Vapour (ACV):</b>	none	
<b>Dermal absorption (DA):</b>	50,00	% ('worst case')	<b>Inhalation Rate (IR):</b>	16,57	m <sup>3</sup> /d (adults),
<b>Inhalation absorption (IA):</b>	100	%		8,31	m <sup>3</sup> /d (children)
<b>Oral absorption (OA)</b>	100	%	<b>Saliva Extraction Factor (SE):</b>	50	%
<b>AOEL</b>	0,04	mg/kg bw/d	<b>Surface Area of Hands (SA):</b>	20	cm <sup>2</sup>
			<b>Frequency of Hand to Mouth (Freq):</b>	20	events/h
			<b>Dislodgeable foliar residues (DFR):</b>	20	%
			<b>Ingestion Rate for Mouthing of Grass/Day (IgR):</b>	25	cm <sup>2</sup> /d

**Table A 26: Estimation of resident exposure towards MCPA**

Adults			Children		
Residents: Dermal exposure after application in Pome and stone fruits (via deposits caused by spray drift)					
$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$			$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$		
$(0,0072 \times 1 \times 3,6\% \times 5\% \times 7300 \times 2 \times 50\%) / 60$			$(0,0072 \times 1 \times 3,6\% \times 5\% \times 2600 \times 2 \times 50\%) / 16,15$		
External exposure	0,1403352	mg/person	External exposure	0,0499824	mg/person
External exposure	0,0023389	mg/kg bw/d	External exposure	0,0030949	mg/kg bw/d
Absorbed dose:	0,0011695	mg/kg bw/d	Absorbed dose:	0,0015474	mg/kg bw/d
Residents: Inhalation exposure to vapour					
$SIE_R = (AC_V \times IR \times IA) / BW$			$SIE_R = (AC_V \times IR \times IA) / BW$		
$(0 \times 16,57 \times 100\%) / 60$			$(0 \times 8,31 \times 100\%) / 16,15$		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		none	Absorbed dose:		none
			Residents: Oral exposure (hand-to-mouth transfer)		

			$SOE_H = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) / BW$ $(0,0072 \times 1 \times 3,6\% \times 5\% \times 50\% \times 20 \times 20 \times 2 \times 100\%) / 16,15$		
			External exposure	0,0038448	mg/person
			External exposure	0,0002381	mg/kg bw/d
			<b>Absorbed dose</b>	<b>0,0002381</b>	<b>mg/kg bw/d</b>
			<b>Residents: Oral exposure (object-to-mouth transfer)</b>		
			$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$ FAŁSZ		
			External exposure	0,0009612	mg/person
			External exposure	5,952E-05	mg/kg bw/d
			<b>Absorbed dose</b>	<b>0,0000595</b>	<b>mg/kg bw/d</b>
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$		
Total systemic exposure (absorbed dose)	0,0701676	mg/person	Total systemic exposure (absorbed dose)	0,0297972	mg/person
<b>Total systemic exposure (absorbed dose)</b>	<b>0,0011695</b>	<b>mg/kg bw/d</b>	<b>Total systemic exposure (absorbed dose)</b>	<b>0,0018450</b>	<b>mg/kg bw/d</b>
<b>% of AOEL:</b>	<b>2,92</b>	<b>%</b>	<b>% of AOEL:</b>	<b>4,61</b>	<b>%</b>

### A 3.4 Combined exposure calculations for glyphosate and MCPA

Table A 27 Risk assessment from combined exposure - operator

	Glyphosate (AOEL = 0,1 mg/kg bw/ day)		MCPA (AOEL = mg/kg bw/ day)		Cumulative risk
Application scenario	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	HI
<b>Orchards: pome and stone fruit, Tree nuts - tractor mounted</b>					
AOEM, With PPE	0.0243	0.24	0.0088	0.22	<b>0.46</b>
<b>Orchards: pome and stone fruit, Tree nuts - handheld application</b>					
German model, With PPE	0.0219	0.22	0.01475	0.37	<b>0.59</b>

Table A 28 Risk assessment from combined exposure – worker

	Glyphosate (AOEL = 0,1 mg/kg bw/ day)		MCPA (AOEL = mg/kg bw/ day)		Cumulative risk
Application scenario	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	HI
<b>Orchards: pome and stone fruit, Tree nuts</b>					
German re-entry model, With PPE	0.0267	0.27	0.00926	0.23	<b>0.50</b>

Table A 29 Risk assessment from combined exposure – resident/bystander

	Glyphosate (AOEL = 0,1 mg/kg bw/ day)		MCPA (AOEL = mg/kg bw/ day)		Cumulative risk
Application scenario	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	HI

Orchards: pome and stone fruit, Tree nuts					
<b>Bystander - adult</b>	0.0464	0.46	0.0160	0.40	<b>0.86</b>
<b>Bystander - child</b>	0.0363	0.36	0.0125	0.31	<b>0.67</b>
<b>Resident - adult</b>	0.00338	0.03	0.00117	0.03	<b>0.06</b>
<b>Resident - child</b>	0.0053	0.05	0.001185	0.05	<b>0.10</b>

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