REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GWN-10616

Chemical active substances:

Zoxamide, 60 g/L

Potassium phosphonates, 755 g/L

Phosphonic acid equivalents, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: XXXX

Submission date: 31/10/2023

Evaluation date: 07/2024 (update 09/2024)

MS Finalisation date: 11/2024

Version history

When	What
July 2024	zRMS finalised dRR evaluation
September 2024	Update based on RMS request of July 2024: • Chapter 8.7 (new PECgw calculations for metabolite RH-141455 based on input parameters accepted by RMS-LV) • Chapter 8.8 (new PECsw calculations for potatoes based on input parameters accepted by RMS-LV)
November 2024	Revised version addressing the comments resived

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

Review Comments:

This document describes the acceptable use conditions required for registration of GWN-10616, a SC formulation containing 60 g/L zoxamide and 755 g/L potassium phosphonates (=500 g/L phosphonic acid) for the use as fungicide in grapevine, pome fruit and potato.

This Part B document only reviews data 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.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**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 safener/synergist per ha (f)	**Groundwater**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha (Z) = Zoxamide (K) = phosphonic acid 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	AT, BE, CZ, HU, NL, PL, RO, SI, SK	Grapevine (table and wine)	F	Downy mildew *Plasmopara viticola*	Broadcast foliar spray	BBCH 14-79	a) 3 b) 3	8-10	a) 3 1.67 L/10000 m^2 tLWA b) 9 5.01 L/10000 m^2 tLWA	a) 180 (Z); 1500 (K) 100 g a.s./ 10000 m^2 tLWA (Z) 835 g a.s./ 10000 m^2 tLWA (K) b) 540 (Z); 4500 (K) 300 g a.s./ 10000 m^2 tLWA (Z) 2505 g a.s./ 10000 m^2 tLWA (K)	200-1000 111 – 557 L/10000 m^2 tLWA	28	Collateral effects on *Botrytis cinerea* Assuming max. 18000 m^2 tLWA per ha ground area	A
2	DE	Grapevine (table and wine)	F	Downy mildew *Plasmopara viticola*	Broadcast foliar spray	BBCH 14-79	a) 2 b) 2	8-10	a) 2.5 1.67 L/10000 m^2 tLWA	a) 150 (Z); 1250 (K) 100 g a.s./ 10000 m^2 tLWA (Z) 835 g a.s./ 10000 m^2 tLWA (K)	200-1000 111 – 557 L/10000 m^2 tLWA	28	Collateral effects on *Botrytis cinerea* Assuming max. 14970 m^2 tLWA per ha ground area	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**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 safener/synergist per ha (f)	**Groundwater**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha (Z) = Zoxamide (K) = phosphonic acid a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
									b) 5 5.01 L/10000 m^2 tLWA	b) 300 (Z); 2500 (K) 300 g a.s./ 10000 m^2 tLWA (Z) 2505 g a.s./ 10000 m^2 tLWA (K)				
3	AT, BE, CZ, HU, NL, PL, RO, SI, SK	Pome fruit	F	*Venturia* sp.	Broadcast foliar spray	BBCH 51-69	a) 2 b) 2	6-8	a) 3 1.67 L/10000 m^2 tLWA b) 6 3.34 L/10000 m^2 tLWA	a) 180 (Z); 1500 (K) 100 g a.s./ 10000 m^2 tLWA (Z) 835 g a.s./ 10000 m^2 tLWA (K) b) 360 (Z); 3000 (K) 200 g a.s./ 10000 m^2 tLWA (Z) 1670 g a.s./ 10000 m^2 tLWA (K)	200-1000 111 – 557 L/10000 m^2 tLWA	NR	Treatments within the end of flowering Assuming max. 18000 m^2 tLWA per ha ground area	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**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 safener/synergist per ha (f)	**Groundwater**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha (Z) = Zoxamide (K) = phosphonic acid a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
4	DE	Pome fruit	F	*Venturia* sp.	Broadcast foliar spray	BBCH 51-69	a) 2 b) 2	6-8	a) 2.5 1.67 L/10000 m^2 tLWA b) 5 3.34 L/10000 m^2 tLWA	a) 150 (Z); 1250 (K) 100 g a.s./ 10000 m^2 tLWA (Z) 835 g a.s./ 10000 m^2 tLWA (K) b) 300 (Z); 2500 (K) 200 g a.s./ 10000 m^2 tLWA (Z) 1670 g a.s./ 10000 m^2 tLWA (K)	200-1000 111 – 557 L/10000 m^2 tLWA	NR	Treatments within the end of flowering Assuming max. 14970 m^2 tLWA per ha ground area	A
5	AT, BE, CZ, IE, NL	Potato	F	Potato late blight *Phytophthora infestans*	Broadcast foliar spray	BBCH 21-89	a) 3 b) 3	7-8	a) 2.5 b) 7.5	a) 150 (Z); 1250 (K) b) 450 (Z); 3750 (K)	200-500	7		~~A~~
6	DE	Potato	F	Potato late blight *Phytophthora infestans*	Broadcast foliar spray	BBCH 21-89	a) 3 b) 3	7-8	a) 2 b) 6	a) 120 (Z); 1000 (K) b) 360 (Z); 3000 (K)	200-500	7		~~A~~
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
Not relevant														

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**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 safener/synergist per ha (f)	**Groundwater**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha (Z) = Zoxamide (K) = phosphonic acid a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Minor uses according to Article 51 (zonal uses)														
Not relevant														
Minor uses according to Article 51 (interzonal uses)														
Not relevant														

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

* 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

Review Comments:

It should be noted that in Applicant's calculations for RH-141455 the formation fraction of 0.504 was used. Nevertheless, in RMS-LV opinion the correct ff value for the metabolite RH-141455 in Mechthildshausen soil is 1 and the correct arithmetic mean ff value is 0.629. Thus, during the comment stage the Applicant is requested to perform additional calculation for metabolite RH-141455 based on accepted by RMS-LV input parameters. These calculations are particularly required to confirm the maximum concentration of RH-141455 in groundwater below threshold of 0.75 µg/L, as assumed in the assessment of relevance of metabolites in part B10.

Explanation for column 15 "Conclusion"

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

Table 8.1-2: Assessed (critical) uses during approval of Zoxamide and Potassium phosphonates (Phosphonic acid equivalent) concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, 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 safener/ 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		
1 covering use 2	AT, BE, CZ, HU, NL, PL, RO, SI, SK covering for DE	Grapevine (table and wine)	F	Downy mildew *Plasmopara viticola*	Broadcast foliar spray	BBCH 14-79	a) 3 b) 3	8-10	a) 3 1.67 L/10000 m^2 tLWA b) 9 5.01 L/10000 m^2 tLWA	a) 180 (Z); 1500 (K) 100 g a.s./ 10000 m^2 tLWA (Z) 835 g a.s./ 10000 m^2 tLWA (K) b) 540 (Z); 4500 (K) 300 g a.s./ 10000 m^2 tLWA (Z) 2505 g a.s./ 10000 m^2 tLWA (K)	200-1000 111 – 557 L/10000 m^2 tLWA	28	
3 covering use 4	AT, BE, CZ, HU, NL, PL, RO, SI, SK covering for DE	Pome fruit	F	*Venturia* sp.	Broadcast foliar spray	BBCH 51-69	a) 2 b) 2	6-8	a) 3 1.67 L/10000 m^2 tLWA b) 6 3.34 L/10000 m^2 tLWA	a) 180 (Z); 1500 (K) 100 g a.s./ 10000 m^2 tLWA (Z) 835 g a.s./ 10000 m^2 tLWA (K) b) 360 (Z); 3000 (K) 200 g a.s./ 10000 m^2 tLWA (Z)	200-1000 111 – 557 L/10000 m^2 tLWA	NR	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, 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/ syner-gist 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		
										1670 g a.s./ 10000 m^2 tLWA (K)			
5 covering use 6	AT, BE, CZ, IE, NL covering for DE	Potato	F	Potato late blight *Phytophthora infestans*	Broadcast foliar spray	BBCH 21-89	a) 3 b) 3	7-8	a) 2.5 b) 7.5	a) 150 (Z); 1250 (K) b) 450 (Z); 3750 (K)	200-500	7	

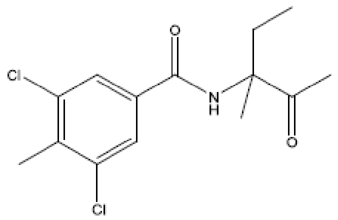
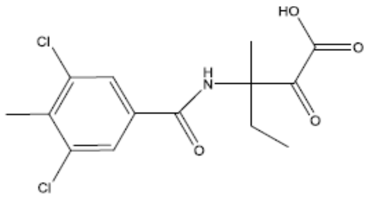
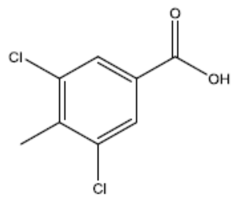
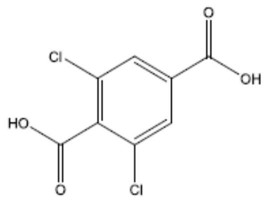
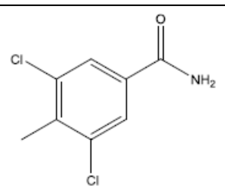
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** 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

8.2 Metabolites considered in the assessment

Metabolites of Zoxamide

Table 8.2-1: Metabolites of Zoxamide potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
RH-127450	302.15		Soil: Max. 15.1% AR after 7 days Water/sediment system: Max. 17.1% AR in surface water (day 28), max. 23.1% AR in sediment max. 39.3% AR in total system (after incubation at 10°C)	PEC_{soil}: occurrence in soil PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: occurrence in surface water
RH-163353	332.15		Soil: Max. 15% AR after 3 days Water/sediment: Max. 15.8% AR at day 28 in the water phase, max. 7.4% AR at day 106 in the sediment, max. 20.6% AR (day 56) in the total system	PEC_{soil}: occurrence in soil PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: occurrence in surface water
RH-24549	205.0		Soil: Max. 33.8% AR after 7 days Water/sediment: Max. 5% AR (whole system)	PEC_{soil}: occurrence in soil PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: occurrence in surface water
RH-141455	235.02		Soil: Max. 8.4% AR after 14 days Water/sediment: Max. 2.1% AR (whole system)	PEC_{soil}: occurrence in soil PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: occurrence in surface water
RH-139432	204.06		Soil: Max. 4.9% AR after 14 days Surface water: Max. 21.4% AR (day 28) in surface water of OECD 309 study (max. of 42.4% AR on day 30 in an aquatic photolysis study at pH 4 is regarded as environmentally not relevant).	$PEC_{sw/sed}$: occurrence in surface water

Metabolites of Potassium phosphonates (Phosphonic acid equivalent)

Phosphate is considered as the only relevant metabolite of Phosphonic acid in soil, surface water and sediment. Based on the criteria laid down in the Sanco/221/2000 – rev.11 (2021), Phosphate is a metabolite of no concern for the groundwater. However, PEC_{sw} and PEC_{sed} values of phosphate ions were calculated for risk assessment of aquatic organisms.

$K^+ + HPO_3^{2-}/H_2PO_3^- + H_2O \rightarrow K^+ + PO_4^{3-} + H_3O^+$

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

The fate and behaviour of Zoxamide in soil is discussed in detail in the document of the EU review dossier (RAR 2017) and the EFSA Conclusion (2017). An additional soil degradation study by Derz (2020) has been performed with the Zoxamide metabolite RH-24549 to gather more detailed information on its degradation and formation fraction (ff) values for its transformation product RH-141455 in three different soils under aerobic conditions in the dark. This study was previously submitted to the RMS Latvia.

Another study on the enantioselective degradation of (R)- and (S)-Zoxamide in one soil incubated under aerobic conditions in the dark is provided (Kercher, 2017). This study has been completed after the peer review of Zoxamide data during active ingredient renewal (AIR) but was considered in the EC Renewal Report (SANTE/10052/2018 rev. 2, dated 23 March 2018).

No new studies have been submitted regarding route and rate of degradation in soil of Potassium phosphonates and Phosphonic acid by the applicant. The EU agreed DT_{50} values of Phosphonic acid based on published and unprotected laboratory studies.

However, a new GLP study on the degradation of Phosphonic acid was submitted for EU approval of the active substance Disodium phosphonate which also forms Phosphonic acid as actual active substance. Furthermore, the quantifiable analyte of the active substance is Phosphonic acid (H_3PO_3). The study was considered acceptable by the RMS and is summarized in the EFSA conclusion for Disodium phosphonate (EFSA Journal 2013;11(5):3213). To base the evaluation of Phosphonic acid on all available data, the DT_{50} values from LoEP of the active substance Disodium phosphonate (see EFSA Journal 2013;11(5):3213) will be used together with the EU approved DT_{50} values submitted for Potassium phosphonates for environmental exposure and risk assessment GWN-10616.

Zoxamide and its metabolites

Degradation of Zoxamide in soil proceeds via enzymatic/microbial degradation. A summary of the pathways is presented in Figure 8.3-1, a list of all potentially relevant metabolites for exposure assessment is provided in Table 8.2-1 of this document.

Major metabolites of Zoxamide (sum of isomers) in soil under aerobic conditions in the dark are RH-127450 (de-chlorinated substance, sum of isomers, ff = 0.19-0.38), RH-24549 (benzoic acid derivative, ff = 0.19-0.57) and RH-163353 (acid, sum of isomers, ff = 0.10-0.23). Maximum levels of these metabolites were found on days 3-14 in aerobic soil degradation studies. Mineralisation to CO_2 was significant (max. = 58% AR). Besides, significant levels of non-extractable residues were formed (25.6-39% AR by days 28-120), associated primarily with humic and fulvic acids and humins. The minor metabolite RH-141455 (3,5-dichloro-4-carboxybenzoic acid) was detected at two different time points above 5% AR with a maximum of 8.4 % in soil (day 14) and is therefore additionally considered. RH-141415 develops from the metabolite RH-24549. For detailed information, please refer to the information provided in the RAR (2017) and the EFSA Conclusion (2017).

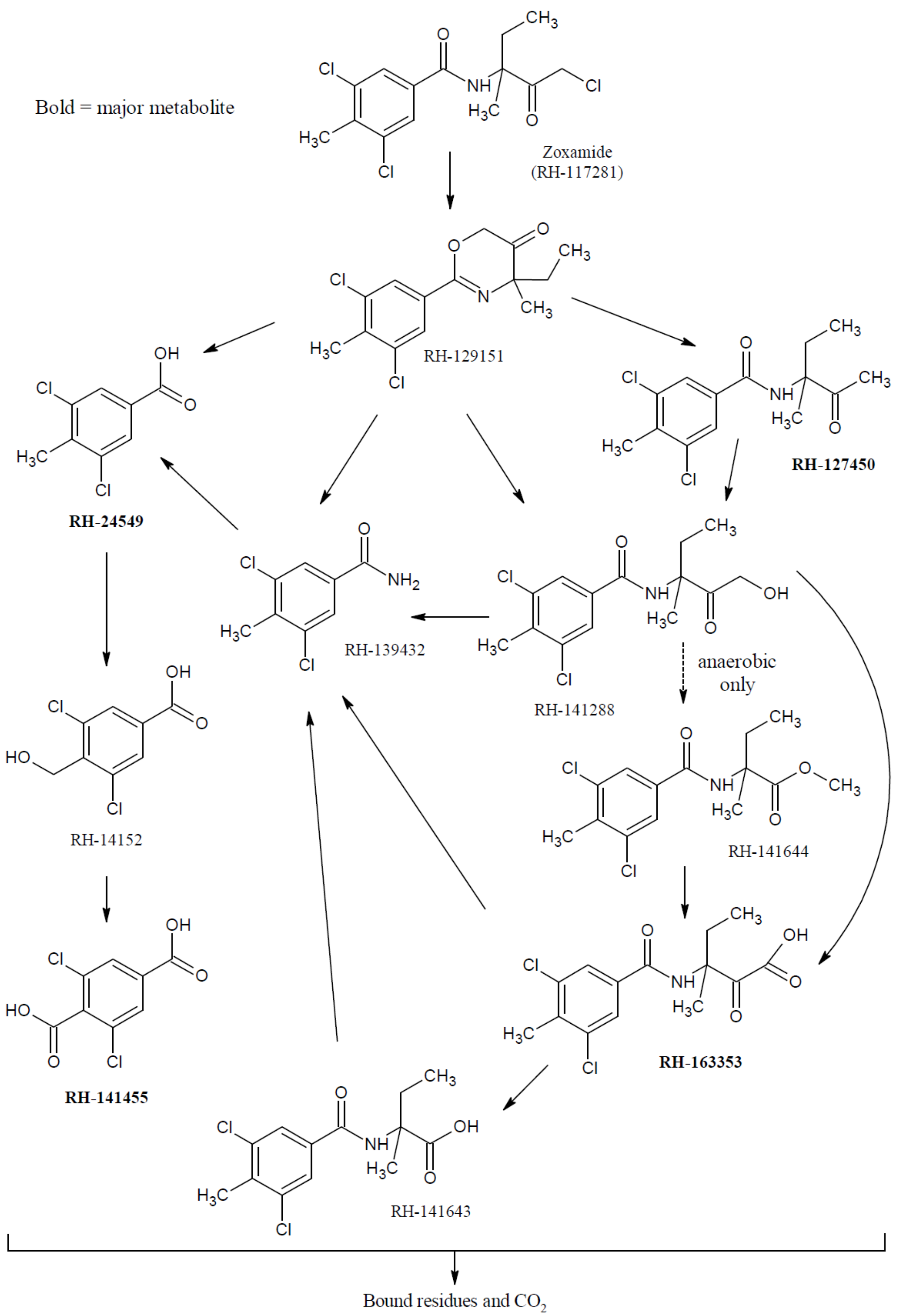


Figure 8.3-1 **Summary of aerobic degradation rates for Zoxamide - laboratory studies**

EFSA conclusion (2017) set a worst-case default formation fraction (ff) of 1 (n=1) for the formation of RH-141455 from RH-24549 based on a study performed with the parent compound Zoxamide with low detections (Table B.8.1.1-1 of Volume 3 Part B. 8 of the RAR for Zoxamide dated May 2017) since only results for one soil were available.

In 2020, a new soil degradation study has been performed with [^{14}C]-RH-24549 by Derz, to gather more detailed information on this formation step under aerobic conditions in the dark. In this new study further degradation rates of RH-24549 (precursor of RH-141455) and RH-141455 (transformation product of RH-24549) as well as formation fractions of RH-141455 developed from RH-24549 were obtained for 3 additional soils. This study was previously submitted to the RMS Latvia and a summary of the study can be found in Appendix 2. The soil degradation values for RH-141455 and RH-24549 out of the study of Derz (2020) have been re-evaluated by Klein & Mendel-Kreusel (2020), normalised to standard reference conditions with regard to soil moisture (pF2) and compared to the values available in the EFSA Conclusion (2017). A summary of the study of Klein & Mendel-Kreusel (2020) can be found in Appendix 2 and was previously submitted to the RMS Latvia, a summary of the overall results for RH-24549 and RH-141455 are listed in Table 8.3-3 and Table 8.3-4.

Review Comments:

The confirmatory-like studies were evaluated by the RMS-LV for zoxamide and its metabolites in an interzonal procedure. All details are to be found in the file: Zoxamide_confirmatory_like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC.

DT_{50} values for Zoxamide and its metabolites are given in the tables below. Geometric mean modelling DT_{50} values were calculated for soils incubated at 20/25°C. Where a number of DT_{50} values were obtained from the same soil (e.g., German sandy loam), only the DT_{50} values derived from the experiment performed under standard incubation conditions (20°C, 100% FC) were taken into account for the calculation of geometric mean.

Table 8.3-1: Summary of aerobic degradation rates for Zoxamide - laboratory studies

Zoxamide, laboratory studies, aerobic conditions										
Soil name or location	**Soil type**	**pH**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C & pF2**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Shelly, England	silt loam	5.0	20	50	3.9	13	3.28	5.68	SFO	Y[1)]
Bordeaux, France	loam	7.4	20	50	1.99	6.62	1.87	7.02	SFO	
St. Margherita, Italy	clay loam	8.1	20	50	2.37	7.87	1.97	6.06	SFO	
Mechthildshausen, Germany	sandy loam	7.4	20	50	2.71	9.01	2.68[2)]	4.65	SFO	
			20	100% FC	2.22	7.38	2.22	6.72	SFO	
			10	50	7.29	24.2	2.81[2)]	6.78	SFO	
Pensylvania, USA	silt loam	6.8	25	75% FC	29.5[3)]	--	34.27	9.2	DFOP (modelling)	
					7.75	98.1	--		DFOP (persistence)	
Ohio; USA	loamy sand	6.9	25	75% FC	28.4	--	31.66	13.5	~~DFOP~~ SFO (modelling)	
					13.6	115	--		DFOP	

Zoxamide, laboratory studies, aerobic conditions										
Soil name or location	**Soil type**	**pH**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C & pF2**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
								3.84	(persistence)	
Geometric mean (n=6)							**5.5**			
pH-dependency:							n			

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] According to EFSA (2017), for the calculation of the geometric mean value only the value for the German sandy loam at 20°C and 100% FC (no normalisation necessary) is considered [3)]DT_{90}/3.32

The geometric mean DT_{50} of 5.5 days (n=6) for Zoxamide in soil was used for surface water and groundwater simulations. For PEC_{soil} calculations the slow-phase DT_{50} of 46.9 days from the DFOP kinetics (k = 0.01477) was considered, as recommended in the FOCUS (1997) document on Soil Persistence Models and EU Registration and in the FOCUS (2006) Kinetics Guidance.

Table 8.3-2: Summary of aerobic degradation rates RH-127450 - laboratory studies

RH-127450, laboratory studies, aerobic conditions										
Soil name or location	**Soil type**	**pH**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C & pF2**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference°**
Shelly, England	silt loam	5.0	20	50	**14.9**	49.5	12.52	9.61	SFO-SFO	Y[1)]
Bordeaux, France	loam	7.4	20	50	3.8	12.6	3.57	8.63	SFO-SFO	
St. Margherita, Italy	clay loam	8.1	20	50	1.99	6.61	1.65	20.1	SFO-SFO	
Mechthildshausen, Germany	sandy loam	7.4	20	50	6.66	22.1	6.59[2)]	19.3	SFO-SFO	
			20	100% FC	5.79	19.2	5.79	23.9	SFO-SFO	
			10	50	18.7	62	7.22[2)]	16.9	SFO-SFO	
Ohio; USA	loamy sand	6.9	25	75% FC	8.27	27.5	9.22	17.7	SFO-SFO	
Geometric mean (n=5)							**5.2**			
pH-dependency:							n			

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] According to EFSA (2017), for the calculation of the geometric mean value only the value for the German sandy loam at 20°C and 100% FC (no normalisation necessary) is considered

For RH-127450 the geometric mean $DegT_{50}$ of 5.2 days (n=5) was used for surface water and groundwater simulations. An arithmetic mean formation fraction (ff) of 0.24 (n=5) from the parent compound Zoxamide was used (please refer to EFSA, 2017). For PEC_{soil} the worst-case half-life at 20°C of 14.9 days was considered for the calculations.

Table 8.3-3: Summary of aerobic degradation rates RH-24549 - laboratory studies

RH-24549, laboratory studies, aerobic conditions										
Soil name or location	**Soil type**	**pH**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C & pF2**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Bordeaux, France	loam	7.4	20	50	6.32	21	5.94	23.2	SFO-SFO	Y[1)]
St. Margherita, Italy	clay loam	8.1	20	50	8.45	28.1	7.01	24.2	SFO-SFO	
Mechthildshausen, Germany	sandy loam	7.4	20	50	5.78	19.2	5.72[2)]	30.7	SFO-SFO	
			20	100 (FC)	3.07	10.2	3.07	16	SFO-SFO	
Ohio, USA	loamy sand	6.9	25	75 (FC)	6.13	20.4	6.83	16.1	SFO-SFO	
RefeSol 01-A	sandy loam	5.7	20	45	11	24.6	8.52	2.22	HS	N[3,4)]
RefeSol 02-A	silt loam	6.8	20	45	8.6	15.9	6.83	1.8	HS	
RefeSol 05-G	loam	4.9	20	45	**13.8**	45.9	13.8	5.98	SFO	
Geometric mean (n=7)							**6.84**			n
pH dependency:							y			Y[1)]

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] According to EFSA (2017), for the calculation of the geometric mean value only the value for the German sandy loam at 20°C and 100% FC (no normalisation necessary) is considered
[3)] Derz, K. (2020). Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia
[4)] Klein, J., Mendel-Kreusel, R. (2020). Recalculation of the degradation of RH-141455 and RH-24549 in soil based on the study data of Derz K. (2020): Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia

In the study of Derz (2020) additional soil degradation data have been generated for RH-24549 under different soil conditions compared to the already available EFSA (2017) values. The half-lives in the EFSA Conclusion (2017) are slightly lower than in the study of Derz (2020), but they are in a comparable range. As a result, for RH-24549 the geometric mean $DegT_{50}$ of 6.84 days (n=7) was used for surface water and groundwater simulations. An arithmetic mean formation fraction (ff) of 0.38 (n=4) from the parent compound Zoxamide was used (please refer to EFSA, 2017). For PEC_{soil} calculations the worst-case half-life of 13.8 days was considered.

Table 8.3-4: Summary of aerobic degradation rates RH-141455 - laboratory studies

RH-141455, laboratory studies, aerobic conditions											
Soil name or location	**Soil type**	**pH**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C & pF2**	**Chi^2 (%)**	**Kinetic model**	**FF**	**Evaluated on EU level y/n/ Reference**
Mechthildshausen, Germany	sandy loam	7.4	20	50	**88.5**	294	87.62	18.2	SFO-SFO	0.50 [1)]	
Speyer 2.2	loamy sand	5.5	20	40	12.0	40.0	12.00	6.95	SFO [3)]	--	Y[2)]
Speyer 2.3	sandy loam	6.8	20	40	11.1	36.9	9.54	5.77	SFO [3)]	--	
Speyer 6S	clay	7.1	20	40	31.7	105.3	14.72	6.8	SFO [3)]	--	
RefeSol 01-A	sandy loam	5.7	20	45	4.02	13.4	3.11	13.2	HS-SFO [4)]	0.3336	
RefeSol 02-A	silt loam	6.8	20	45	1.12	3.72	0.89	29.1	HS-SFO [4)]	0.3988	N[5,6)]
RefeSol 05-G	loam	4.9	20	45	3.22	10.7	3.22	14.8	SFO-SFO [4)]	0.7822	
Geometric mean (n=7)							**7.48**				n
Arithmetic mean (n=4)										**0.504**[4] / **0.629**[5]	
pH-dependency:							n				Y[2)]

1) From the study of Burgener 1998 with the parent compound Zoxamide the ff from RH-24549 was calculated at 0.5, but set to a default value of 1 by EFSA (2017)[2)]
2) EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
3) Study conducted with RH-141455
4) Study conducted with RH-24549 as precursor of RH-141455
5) Derz, K. (2020). Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia.
6) Klein, J., Mendel-Kreusel, R. (2020). Recalculation of the degradation of RH-141455 and RH-24549 in soil based on the study data of Derz K. (2020): Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia.
4 value not accepted by RMS-LV, please see file: Zoxamide_ confirmatory_ like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC
5 calculated considering a formation fraction of 1.0 for Mechthildshausen soil

The Zoxamide metabolite RH-141455 develops from its precursor RH-24549. From the soil degradation study of Burgener (1998) with the parent compound Zoxamide a formation fraction (ff) of 0.50 for RH-141455 developed from RH-24549 was determined but set to a default value of 1 (n=1) by EFSA (2017) (please refer to Volume 3 Part B. 8 of the final RAR for Zoxamide, 2017). The study of Derz (2020) with [^{14}C]-RH-24549 as test item investigated further the formation fraction and degradation behaviour. As a result, an overall arithmetic mean formation fraction of 0.504 (n=4) was found for the transformation of RH-24549 to RH-141455 together with a geometric mean $DegT_{50}$ value of 7.48 days (n=7). The geometric mean $DegT_{50}$ of 7.48 days (n=7) and the arithmetic mean formation fraction (ff) of 0.504 (n=4) was used for surface water and groundwater simulations. For PEC_{soil} calculations the worst-case half-life of 88.5 days was considered.

The DT_{50} values for the soil metabolite RH-141455 available from Derz (2020) are shorter than in the EFSA Conclusion (2017), but reliable and applicable for PEC_{gw} and PEC_{sw} calculations. For further information please refer to Klein & Mendel-Kreusel (2020; report no. GOW0720-1), which summary can be found in Appendix 2 of this document.

Table 8.3-5: Summary of aerobic degradation rates RH-163353 - laboratory studies

RH-163353, laboratory studies, aerobic conditions										
Soil name or location	**Soil type**	**pH**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C & pF2**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Shelly, England	silt loam	5.0	20	50	**49.7**	165	41.75	7.38	SFO-SFO	Y[1)]
Bordeaux, France	loam	7.4	20	50	6.65	22.1	6.25	25.2	SFO-SFO	
St. Margherita, Italy	clay loam	8.1	20	50	6.4	21.3	5.31	7.2	SFO-SFO	
Mechthildshausen, Germany	sandy loam	7.4	20	50	5.62	18.7	5.56[2)]	17.2	SFO-SFO	
			20	100% FC	9.96	33.1	9.96	13.8	SFO-SFO	
			10	50	55.6	185	21.47[1]	17.5	SFO-SFO	
Geometric mean (n=4)							**10.8**			
pH-dependency:							n			

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980

[2)] According to EFSA (2017), for the calculation of the geometric mean value only the value for the German sandy loam at 20°C and 100% FC (no normalisation necessary) is considered

For RH-163353 a geometric mean $DegT_{50}$ of 10.8 days (n=4) was used for surface water and groundwater simulations. An arithmetic mean formation fraction (ff) of 0.18 (n=4) from the parent compound Zoxamide was used (please refer to EFSA, 2017). For PEC_{soil} the worst-case half-life of 49.7 days was considered for the calculations.

The enantioselective degradation of (R)- and (S)-Zoxamide in one soil incubated under aerobic conditions in the dark has been investigated by Kercher (2017). A summary of the study can be found in Appendix 2. This study has been completed after the peer review of Zoxamide data during AIR and considered in the EC Renewal Report (SANTE/10052/2018 rev. 2, dated 23 March 2018) showing, that there is no difference in rate of degradation of the isomers of neither Zoxamide nor the major soil metabolite 127450.

Meanwhile, the chemical stability of the chiral carbon of Zoxamide and its racemic metabolites has been demonstrated in a range of studies and matrices.

Potassium phosphonates

Table 8.3-6: Summary of aerobic degradation rates for Phosphonic acid - laboratory studies

Phosphonic acid, Laboratory studies, aerobic conditions										
Soil name	**Soil types**	**pH (n.i.)**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**r2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
San Joaquin	clay loam	not stated	28	field capacity	96	319	**196**	0.96	SFO	Y[1)]
US sandy loam	sandy loam	5	20	75% of 33 kPa	133	442	88	0.68	SFO	
Clay loam	clay loam	7.5	20	pF 2.0-2.5	179	750	-	-	SFO	Y[2)]
					246	-	246	0.975	DFOP slow phase	
Sandy loam	sandy loam	6.3	20	pF 2.0-2.5	191	843	-	-	SFO	
					280.6	-	280.6	0.979	DFOP slow phase	
Silt loam	silt loam	7.7	20	pF 2.0-2.5	29.65	98.5	29.7	-	SFO	
Geometric mean (n=5)							128.8 d			
pH-dependency: n										

1) EFSA (2012): Conclusion on the peer review of the pesticide risk assessment of the active substance Potassium phosphonates. EFSA Journal 2012, 10 (12):2963
2) EFSA (2013): LoEP Disodium phosphonate EFSA Journal 2013;11(5):3213.

For Phosphonic acid the worst-case LoEP DT_{50} of 196 days was used for surface water and groundwater simulations. For PEC_{soil} the worst-case LoEP half-life at 20°C of 196 days was considered for the calculations. In order to base the evaluation of Phosphonic acid on all available data, an additional assessment is submitted considering the worst case biphasic degradation $DT_{50,fast}$= 9.19 days and $DT_{50,slow}$ = 280.6 days from LoEP for Disodium phosphonate (EFSA Journal 2013;11(5):3213).

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

In an anaerobic environment, mineralisation of Zoxamide was shown to be slow, below 0.1% AR. Non-extractable soil residues amounted to 26.4% AR after day 120. Levels of organic volatiles were below 0.1% AR. Levels of non-extracted radioactivity were 0.1% AR on day 0, increasing to 26.4% AR by day 120. Zoxamide exhibited low persistence forming the major metabolites RH-127450 (max. 30% AR), RH-24549 (max. 24% AR) and the novel metabolites compared to aerobic conditions RH-141288 (max. 5.5% AR) and unidentified M25 (max. 6.3% AR) and M15 (max. 6.6% AR). It is unlikely that anaerobic conditions are encountered after application of Zoxamide to the intended crops with application according to GAP. For more detailed information, please refer to the RAR (2017) and the EFSA Conclusion (2017).

For the anaerobic degradation in soil of Potassium phosphonates and Phosphonic acid, no reliable data were provided within Annex I inclusion. Qualitative data demonstrated that microbial culture of some soil micro-organisms could convert phosphonic acid / (phosphite) to organic phosphate products, though this did not occur when phosphate was present. For more details, please refer to the EFSA Conclusion (2012).

8.3.3 Field studies (KCP 9.1.1.2)

Studies on field dissipation rates with the formulation were not performed, since it is possible to extrapolate from data obtained for the active substances. For active substance Zoxamide, please refer to the information in the RAR (2017) and the EFSA Conclusion (2017). For active substance Potassium phosphonates, please refer to the EFSA Conclusion (2012).

8.3.4 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Zoxamide and its metabolites

No studies are required since DT_{50} values from laboratory studies are <60 days for Zoxamide and its metabolites. Therefore, endpoints from field soil dissipation studies are not available.

Potassium phosphonates

For Phosphonic acid, no studies are provided. For details, please refer to the EFSA Conclusion (2012) for Potassium phosphonates.

8.3.5 Soil accumulation testing (KCP 9.1.1.2.2)

The DT_{90} value of Zoxamide and its metabolites is less than 365 days. Therefore, no studies are triggered.

For Potassium phosphonates and Phosphonic acid it is possible to extrapolate from data provided for the active substance. Data on soil accumulation are addressed by PEC_S calculations and laboratory soil degradation studies of Phosphonic acid.

8.4 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

8.4.1 Zoxamide and its metabolites

The adsorption/desorption behaviour of the active substance Zoxamide was evaluated during the process of the renewal of approval under Article 14 of Regulation (EC) No 1107/2009 the RAR (2017) and the EFSA Conclusion (2017). The following information is available on EU level and was used for PEC calculations.

Table 8.4-1: Summary of soil adsorption/desorption for Zoxamide

Zoxamide							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Huntsburg, Ohio, USA	loam	1.27	7.2	10.35	815	0.896	Y[1)]
Concord, Ohio, USA	silty clay loam	1.77	4.8	25.33	1431	0.963	
Madison, Ohio, USA	sandy loam	1.1	6.7	15.23	1385	0.953	
Newtown, Pennsylvania, USA	silty loam	1.04	6.8	12.44	1196	1.067	
Arithmetic mean / geometric mean (n=4)					1207/ **1179**	**0.970/** 0.968	
pH-dependency					n		

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980

Table 8.4-2: Summary of soil adsorption/desorption for RH-127450

RH-127450							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Borstel, Germany	loamy sand	1.05	6.1	12.14	1156	0.519	Y[1)]
Egerkingen, Switzerland	clay	2.82	5.0	11.4	404	0.603	
Vetroz, Switzerland	silt loam	4.05	7.3	18.12	447	0.448	
Arithmetic mean / geometric mean (n=3)					669 / **593**	**0.9**[2)]	
pH-dependency					n		

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] The calculated Freundlich exponent of 0.523 was considered unreliable, therefore a 1/n value of 0.9 was considered appropriate for modelling according to EFSA LoEP (2017)

Table 8.4-3: Summary of soil adsorption/desorption for RH-24549

RH-24549							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Iowa/USA	sandy loam	1.3	5.2	4.0	307.43	0.791	Y[1)]
Illinois/USA	silty clay loam	2.4	7.3	3.6	150.16	0.833	
Ohio/USA	silt loam	2.0	7.6	1.8	**90.55**[2)]	**0.811**	
Arithmetic mean / geometric mean (n=3)					183 / 161	0.811	
pH-dependency					y		

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)]Adsorption of RH-24549 is pH dependent. Consequently, the worst-case K_{foc} is considered for modelling according to EFSA LoEP (2017)

Table 8.4-4: Summary of soil adsorption/desorption for RH-141455

RH-141455							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	loamy sand	1.87	5.5	0.06	3.1[2)]	1.0[2)]	Y[1)]
Speyer 2.3	sandy loam	0.94	6.8	0.03	3.3[2)]	1.0[2)]	
Speyer 6S	clay	1.64	7.1	0.03	2.1[2)]	1.0[2)]	
Arithmetic mean (n=3) / geometric mean (n=3)					2.8 / **2.8**	**1.0**	
pH-dependency					n		

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] K_{oc} derived from a K_d from an OECD 106 screening study, in which 1/n values were not measured. Therefore, a default 1/n value of 1.0 is assumed for modelling according to EFSA LoEP (2017)

Table 8.4-5: Summary of soil adsorption/desorption for RH-163353

RH-163353							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Borstel, Germany	loamy sand	1.22	6.1	0.6	50[2)]	1.0[2)]	Y[1)]
Egerkingen, Switzerland	clay	3.17	5.4	2.4	75	0.833	
Vetroz, Switzerland	silt loam	4.79	7.2	3.8	79	0.844	
Arithmetic mean / geometric mean (n=3)					68 / **67**	**0.892**	
pH-dependency					n		

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] K_{oc} derived from a K_d from a screening study, in which 1/n values were not measured. Therefore, a default 1/n value of 1.0 is assumed according to EFSA LoEP (2017)

8.4.2 Potassium phosphonates

The adsorption/desorption behaviour of the active substance Potassium phosphonates was evaluated during the Annex I Inclusion procedure. For Phosphonic acid, the LoEP K_d values based on a GLP study is used. For details, please refer to the EFSA conclusion (2012). The available adsorption data of Phosphonic acid used for environmental exposure and risk assessment are summarized in Table 8.5-6.

Table 8.4-6: Summary of soil adsorption/desorption for Phosphonic acid

Phosphonic acid							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_d (mL/g)**	**K_{oc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Mechthildshausen	loam	1.36	6.8	3.10	228	-	Y[1)]
Mussig	clay loam	4.13	7.6	10.37	251	-	
Uffholtz	silty clay loam	2.67	5.0	15.67	587	-	

Phosphonic acid							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_d (mL/g)**	**K_{oc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	sandy loam	2.3	5.6	5.30	230	-	
Bretagne	silt loam	1.95	5.5	18.96	972	-	
Arithmetic mean / geometric mean (n=5)				10.7/ 8.73			
pH-dependency					n		

[1)] EFSA (2012): Conclusion on the peer review of the pesticide risk assessment of the active substance Potassium phosphonates. EFSA Journal 2012, 10 (12):2963

8.4.3 Column leaching (KCP 9.1.2.1)

Based on the data presented in chapter 8.5.1 of this document, it is not required to conduct and report soil column leaching studies since reliable adsorption coefficient values are available for Zoxamide and its metabolites.

However, aged residue leaching experiments (aged for 3 days, followed by a study period of 2 days) have been performed. As a result, 1.8-2.3% of the applied radioactivity (AR) appeared in the leachate, 68.6-74.4% AR retained in the top 0-5 cm layer. The active substance Zoxamide stayed at 12.3-16.5% in the top 0-5 cm and was undetectable in the 5-20 cm layer. The soil metabolite RH-127450 was determined at 6.9-11.9% AR in the top 0-5 cm soil layer, at ≤0.3% AR in the 5-10 cm soil layer and was undetectable in 10-20 cm layer. The metabolite RH-24549 was analysed at 5.6-8.8% AR in the 0-5 cm soil layer and at 0.3-1.9% AR in the 15-20 cm layer. RH-163353 occurred at 4-6.7% AR in the top 0-5 cm and at 0.5-0.7% AR in the 15-20 cm soil layer.

For active substance Potassium phosphonates, reliable adsorption coefficient values were obtained from studies for Phosphonic acid, as outlined above. Based on these data presented in chapter 8.5.1 of this document, it is not necessary to conduct and report soil column leaching studies since reliable adsorption coefficient values are available for Potassium phosphonates.

8.4.4 Lysimeter studies (KCP 9.1.2.2)

No lysimeter or field leaching studies have been conducted for Zoxamide and its metabolites. The leaching behaviour of Zoxamide and its metabolites is adequately assessed using mathematical modelling.

As it is possible to extrapolate from data provided on Potassium phosphonates, no further studies are provided on the preparation. Since Phosphonic acid does not pose any risk for groundwater contamination according to the drinking water guidance by WHO, no lysimeter studies are triggered and therefore, no studies were required.

8.4.5 Field leaching studies (KCP 9.1.2.3)

No lysimeter or field leaching studies have been conducted for Zoxamide and its metabolites. The leaching behaviour of Zoxamide and its metabolites is adequately assessed using mathematical modelling. No lysimeter or field leaching studies have been conducted for Potassium phosphonates and its metabolites. The leaching behaviour of Phosphonic acid is adequately assessed using mathematical modelling.

8.5 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

The degradation in water/sediment systems of the active substance Zoxamide was evaluated during the process of the renewal of approval and is discussed in detail in the document of the EU review dossier (RAR 2017) and the EFSA Conclusion (2017).

No reliable data for water/sediment system with Potassium phosphonates were submitted for EU approval, as this is not applicable to an inorganic salt that is in water dissociated not hydrolysed. Moreover, it is expected that Phosphonic acid is rapidly adsorbed to the sediment where it could slowly be oxidized to phosphate.

8.5.1 Zoxamide and its metabolites

The major dissipation routes of Zoxamide in water/sediment systems are hydrolysis, microbial degradation, partitioning to sediment and photolysis, which plays a minor role.

Zoxamide degrades hydrolytically with a DT_{50} of 16 days (1^{st} order, $r^2 = 1.0$) at pH 7 and 25°C, where the metabolite RH-24549 occurred at max. amount of 20.75% AR on day 30 during the laboratory experiment and was shown to be hydrolytically stable at pH 7 and 25°C. Additionally, for environmental assessment non relevant, metabolite RH-141288 occurred at max. amount of 21.9% AR on day 30 during the laboratory experiment with the parent compound and was found to be hydrolytically stable at pH 7 and 25°C. Also, the metabolite RH-129151 with a DT_{50} of 9.1 days was detected at max. of 24.5% at pH 7 on a day 21 and the metabolite RH-150721 was detected at a max. of 1.5% AR at pH 7 on day 30.

At pH 4 and under light (equivalent to light intensity of New Jersey summer sunlight, 42° N), Zoxamide degraded with a DT_{50} of 8 days (12-hour photoperiod) and 22 days in dark control (1^{st} order, $r^2 = 0.99 – 1.0$). The metabolite RH-24549 was detected with max. level of 27.69% AR on day 30, but it not considered as photolysis product as similar levels were measured in dark controls. The metabolite RH-139432 was detected with max. level of 42.4 % AR at day 30. Additionally, for environmental assessment non relevant, metabolite RH-150721 occurred at max. amount 15.10% AR at day 10. Since these metabolite concentrations were only derived at a pH of 4, they are not relevant for natural conditions.

In a study of van den Bosch (2014) according to OECD 309 guideline, the degradation of Zoxamide was examined in surface water (pelagic test), where Zoxamide metabolised rapidly with a DT_{50} of 7.6 to 8.4 days at 20°C and a pH of 7.1-8.4 forming metabolites RH-141455, RH-139432, RH-141288, RH-163353, and RH-24549 detected at maximum amounts of ≥ 10%.

Table 8.5-1: Summary of degradation of Zoxamide during aerobic mineralisation in surface water

System	Model / Temp.	DT_{50}	DT_{90}	Chi^2 (%)	P/confidence interval acceptable?	Evaluated on EU level y/n/ Reference
High dose	SFO / 20°C	7.6	25.4	12.1	Y	Y[1)]
	SFO / 7.5°C[1]	24.9	83.1		Y	
	SFO / 12°C[1]	16.1	54		Y	
Low dose	SFO / 20°C	8.4	28.0	21.9	Y	
	SFO / 7.5°C[1]	27.5	91.6		Y	
	SFO / 12°C[1]	17.8	59.5		Y	

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980

Table 8.5-2: Summary of observed metabolites of Zoxamide – aerobic mineralisation in surface water

RH-141455	Max. in surface water at 10.5% AR (day 44)	Evaluated on EU level: Y[1)]
RH-139432	Max. in surface water at 21.4% AR (day 28)	
RH-141288	Max. in surface water at 22.1% AR (day 58)	
RH-163353	Max. in surface water at 47.9% AR (day 28)	
RH-24549	Max. in surface water at 22.7% AR (day 58)	
M-7	Max. in surface water at 9.1% AR (day 58), but was multicomponent, consisting of 2-3 different substances which individually did not exceed 5% AR.	

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980

In water/sediment system study, a decline of Zoxamide and its metabolite RH-127450 was studied at 10 and 20°C, where Zoxamide was rapidly lost from the water phase, with maximum levels of 30.2 % AR (pond system, 10°C, day 7) and 23.1 % AR occurring in sediment (pond system, 20°C, day 7), declining thereafter. Major metabolites formed were identified as RH-127450 (derivative of parent, dechlorinated in alkyl chain) and RH-163353 (carboxylic acid derivative).

Metabolite RH-127450 increased from zero to maximum levels of 17.1% AR (day 28, river, at 10°C) and 23.1% AR (day 56, river, at 10°C) in water and sediment and then declined. At 20°C RH-127450 occurred with max. 12.8% AR at day 14 (river) in the water phase and max 22.1% AR at day 56 (pond) in the sediment phase and max. 30.0% AR at day 28 (river) in the total system. For RH-127450 a formation fraction (ff) of 0.24 - 0.33 from parent compound was concluded by EFSA (2017).

Metabolite RH-163353 increased from zero to maximum levels of 15.8% AR at day 28 in the water phase (river, 20°C) and max. 13.8% AR at day 106 in the sediment phase (pond, 10°C) and max. 28% AR at day 106 in the total system (river, 10°C). At 20°C its max. occurrence was 7.4% AR at day 106 in the sediment phase (river) and 20.6% AR at day 56 in the total system (river).

The rates of degradation of Zoxamide and RH-127450 in the water/sediment systems (study of Morgenroth, 1998) have been re-evaluated during AIR according to the recommendations of the FOCUS Kinetics Guidance Document (FOCUS, 2006). The results are summarised in the following tables. An acceptable fit for the data of RH-163353 could not be obtained.

Six minor metabolites were tentatively identified and eighteen unidentified degradates were found. The total levels of these compounds in any system, at any time point, were individually < 8% AR. Of the non-extractable radioactivity in sediment, 16-20% AR was associated with fulvic acid fraction, 8-13% AR with humic acid fraction and 9-10% AR was found in the insoluble humin fraction.

Table 8.5-3: Summary of degradation of Zoxamide in water/sediment systems

Zoxamide was rapidly lost from the water phase, with maximum levels occurring in sediment of 30.2 % AR (pond system, 10°C, day 7) and 23.1 % AR (pond system, 20°C, day 7), declining thereafter.											
Water/ sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Chi^2 (%)**	**$DissT_{50}$ sed. (d)**	**Chi^2 (%)**	**Method of calcu-lation**	**Evaluated on EU level y/n/ Reference**
River, 20°C	8.39/ 7.4	6.4	21.1	5.921	FOCUS P-II calculations not performed					SFO	Y[1)]
Pond, 20 °C	8.09/ 7.0	6.3	20.9	6.044							
River, 10°C	8.34/ 7.4	10.4	34.7	2.59							
Pond, 10°C	8.12/ 7.0	19.4	64.6	3.424							
Arithmetic mean, 20°C (n=2)[2)]		**6.4**	--								

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] For 20 °C experiments.

Table 8.5-4: Summary of degradation of RH-127450 in water/sediment systems

RH-127450 - Distribution with max. of 17.1% in water on day 28 (river, 10°C) and 23.1% in sediment on day 56 (river, 10°C). Max. of 39.3% AR in total system on day 56 (river, 10°C). Formation fraction from parent: 0.24-0.33.											
Water/ sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Chi^2 (%)**	**$DissT_{50}$ sed. (d)**	**Chi^2 (%)**	**Method of calcu-lation**	**Evaluated on EU level y/n/ Reference**
River, 20°C	8.39/ 7.4	148.4	493.1	16.271	Calculations not performed					SFO	Y[1)]
Pond, 20 °C	8.09/ 7.0	326.1	1083.3	7.265							
River, 10°C	8.34/ 7.4	--	--	--							
Pond, 10°C	8.12/ 7.0	123	408.7	20.12							
Geometric mean at 20 °C (n=2) [2)]		237	--								

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] For 20°C experiments.

Table 8.5-5: Summary of observed metabolites of Zoxamide

RH-127450	Max. at 17.1% in water on day 28 (river, 10°C) and 23.1% in sediment on day 56 (river, 10°C). Max. of 39.3% AR in total system on day 56 (river, 10°C). At 20°C max. 12.8% on day 14 (river) in the water and max 22.1% on day 56 (pond) in the sediment and max. 30.0% on day 28 (river) in the total system.	Evaluated on EU level Y[1)]
RH-163353	Max. 15.8% on day 28 in the water phase (river, 20°C) and max. 13.8% on day 106 in the sediment (pond, 10°C). Max. 28% in the total system on day 106 (river, 10°C). At 20°C max. 7.4% on day 106 in the sediment (river) and max. 20.6% on day 56 in the total system (river).	

1) EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980

8.5.2 Potassium phosphonates

No reliable data for water/sediment system with Potassium phosphonates were submitted for EU approval, as this is not applicable to an inorganic salt that is in water dissociated not hydrolysed. Moreover, it is expected that Phosphonic acid is rapidly adsorbed to the sediment where it could slowly be oxidized to phosphate.

Consequently, two environmental exposure assessments were carried out. The first assumed slow oxidation of salts of Phosphonic acid to phosphate ions in receiving water and sediment. The second assumed complete oxidation to phosphate ions.

8.6 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Review Comments:

The PEC_{soil} calculations for zoxamide, its metabolites, potassium phosphonates/phosphonic acid and the formulation GWN-10616 were provided by the Applicant and are considered acceptable. The EU agreed endpoints and the confirmatory-like study by Derz, 2020 evaluated and accepted by the RMS-LV for zoxamide metabolites in an interzonal procedure, were used for PEC_{soil} calculations. Those values are considered acceptable.

The PEC_{soil} reported below can be used for the risk assessment of the non-target organisms. Please refer to Section B9.

8.6.1 Justification for new endpoints

For the $DegT_{50}$ of Zoxamide in soil, EFSA (2017) considered DFOP kinetics in contrast to FOCUS (1997). Instead, we present calculations based on SFO kinetics using the slow phase of DFOP, which is considered to be in accordance with FOCUS (1997) and FOCUS (2006) and can be seen as worst-case compared to the selection of EFSA (2017). Thus, for PEC_{soil} calculations the slow-phase DT_{50} of 46.9 days from the DFOP kinetics (k = 0.01477) was considered.

Based on the EU review dossier (RAR 2017) and the EFSA Conclusion (2017) Zoxamide metabolites RH-127450, RH-24549, RH-163353 and RH-141455 are considered relevant for PEC_{soil} assessment. For metabolites RH-127450 and RH-163353 only EU agreed endpoints were used for the calculation of PEC_{soil}.

An additional soil degradation study (Derz, 2020) has been performed with the Zoxamide metabolite RH-24549 to gather more detailed information on its degradation and the DT_{50} values formation fraction (ff) values of its transformation product RH-141455 in three different soils under aerobic conditions in the dark. This study was previously submitted to the RMS Latvia.

Review Comments:

The confirmatory-like study by Derz, 2020 was evaluated and accepted by the RMS-LV for zoxamide metabolites in an interzonal procedure. All details are to be found in the file: Zoxamide_ confirmatory_ like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC.

According to the EFSA conclusion (2012) for Potassium phosphonates, the Phosphonic acid equivalent is relevant for soil exposure assessment. Two sets of Phosphonic acid PEC_{soil} assessment are provided within this dRR. In the first Phosphonic acid PEC_{soil} assessment the worst-case LoEP half-life at 20°C of 196 days was considered. In order to base the evaluation of Phosphonic acid on all available data, the second assessment is submitted considering the worst case biphasic degradation at 20°C with $DT_{50,fast}$ of 9.19 days and $DT_{50,slow}$ of 280.6 days from the LoEP 2013 for Disodium phosphonate (EFSA Journal 2013;11(5):3213). The study was conducted with Na_2HPO_3 liquid solution, which also forms Phosphonic acid. The study was previously considered acceptable by the RMS.

Due to the slow degradation of Phosphonic acid in soil (DT_{90}>365 d, DFOP, maximum, laboratory data) the accumulation potential of Phosphonic acid needs to be considered. Therefore, an accumulated soil concentration ($PEC_{accumulation}$) is used for risk assessment that comprises background concentration in soil ($PEC_{soil\ plateau}$) considering a tillage depth of 20 cm (arable crop)/5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 5 cm.

PEC_{soil} calculations are based on the recommendations of the FOCUS workgroup on degradation kinetics considering the worst-case interception rates were derived according to the GAP and EFSA (2014). A soil bulk density of 1.5 g/cm^3, a soil depth of 5 cm and a tillage depth of 20 cm (arable crop)/5 cm (permanent crops) were assumed. The metabolites were assessed separately as pseudo parent. The relative "pseudo" application rates of the metabolites used were calculated on a molar basis combined with the application rate of the parent compound and the max. occurrence in soil. The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in tables below.

PEC_{soil} for Zoxamide and its metabolites are presented in Tables 8.7-3 to 8.7-17. Raw data to predicted environmental concentrations in soil for Zoxamide and its metabolites are summarised in Anonymous (2023), Doc. No. 782-003, KCP 9.1.3/01. PEC_{soil} for Phosphonic acid are presented in Tables 8.7-18 to 8.7-23. Raw data to predicted environmental concentrations in soil for Phosphonic acid are summarised in Anonymous (2023), Doc. No. 782-004, KCP 9.1.3/02.

8.6.2 Active substances and relevant metabolites

The formulated product GWN-10616 containing the active substances Zoxamide and Phosphonic acid is intended to be applied to the grapevines, pome fruit and potatoes according to the GAP (see Table 8.1-1). Worst case interception rates were derived according to the GAP and EFSA (2014). Deposition rates and worst case DT_{50} values used are presented in Table 8.7-1 and 8.7-2.

Table 8.6-1: Input parameters related to application for PEC_{soil} calculation

Use No.	1 covering 2	3 covering 4	5 covering 6
Crop	Vines	Pome fruit	Potatoes
Application rate (g a.s./ha)	Zoxamide: 180 Phosphonic acid: 1500	Zoxamide: 180 Phosphonic acid: 1500	Zoxamide: 150 Phosphonic acid: 1250
Number of applications/interval	3/8	2/6	3/7
Crop interception (%)	60, worst case	60, worst case	60, worst case
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (5 cm)	5 cm (5 cm)	5 cm (20 cm)

Table 8.6-2: Input parameter for active substances and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Zoxamide	336.65	-	46.9 (slow phase DFOP in lab, k=0.01477)	Y [1*)]
Metabolite RH-127450	302.15	15.1	14.9	Y [1)]
Metabolite RH-24549	205	33.8	13.8	N [2)]
Metabolite RH-163353	332.15	15	49.7	Y [1)]
Metabolite RH-141455	235.02	8.4	88.5	Y [1)]
Phosphonic acid	80.5	-	196	Y [3)], worse case, SFO
		-	$DT_{50,fast}$= 9.19 $DT_{50,slow}$ = 280 g = 0.2011	DFOP, Maximum, Laboratory data Y [4)] biphasic

[1)] EFSA conclusion on the peer review of the active substance Zoxamide EFSA (2017)
[*]EFSA (2017) considers DFOP kinetics in contrast to FOCUS (1997). Here, calculations are based on SFO kinetics using the slow phase of DFOP which is considered to be in accordance with FOCUS (1997) and FOCUS (2006). It can be also considered as worst-case compared to the selection of EFSA (2017).
[2)] Derz, K. (2020), Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia
[3)] EFSA conclusion on the peer review of the active substance Potassium phosphonates EFSA (2012)
[4)] Worst case dataset including information from EFSA conclusion on the peer review of the active substance Potassium phosphonates EFSA (2012) and EFSA conclusion on the peer review of the active substance Dissodium phosphonate EFSA (2013)

8.6.2.1 PEC_{soil} Zoxamide and its metabolites

Table 8.6-3: PEC_{soil} for Zoxamide on vines

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.2571	-
Short term	24h	0.2533	0.2552
	2d	0.2496	0.2533
	4d	0.2423	0.2496
Long term	7d	0.2318	0.2442
	14d	0.2090	0.2322
	21d	0.1885	0.2220
	28d	0.1700	0.2119
	50d	0.1228	0.1892
	100d	0.0586	0.1456
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-4: PEC_{soil} for Zoxamide on pome fruit

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.1839	-
Short term	24h	0.1812	0.1825
	2d	0.1785	0.1812
	4d	0.1733	0.1785
Long term	7d	0.1658	0.1714
	14d	0.1495	0.1661
	21d	0.1348	0.1581
	28d	0.1215	0.1511
	50d	0.0878	0.1309
	100d	0.0419	0.0994
Plateau concentration (5 cm)		-	-

$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)	-	-

Table 8.6-5: PEC_{soil} for Zoxamide on potatoes

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.2172	-
Short term	24h	0.2140	0.2156
	2d	0.2109	0.2140
	4d	0.2047	0.2109
Long term	7d	0.1958	0.2063
	14d	0.1766	0.1962
	21d	0.1592	0.1876
	28d	0.1436	0.1791
	50d	0.1037	0.1593
	100d	0.0495	0.1220
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

PEC_{soil} of metabolites

Table 8.6-6: PEC_{soil} for RH-127450 on vines

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0282	-
Short term	24h	0.0269	0.0275
	2d	0.0257	0.0269
	4d	0.0234	0.0257
Long term	7d	0.0203	0.0242
	14d	0.0147	0.0215
	21d	0.0106	0.0204
	28d	0.0077	0.0187
	50d	0.0028	0.0146
	100d	0.0003	0.0084
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-7: PEC_{soil} for RH-127450 on pome fruit

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0228	-
Short term	24h	0.0218	0.0223
	2d	0.0208	0.0218
	4d	0.0190	0.0209
Long term	7d	0.0165	0.0195
	14d	0.0119	0.0171
	21d	0.0086	0.0153
	28d	0.0062	0.0139
	50d	0.0022	0.0100
	100d	0.0002	0.0056
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-8: PEC_{soil} for RH-127450 on potatoes

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0243	-
Short term	24h	0.0232	0.0238
	2d	0.0222	0.0232
	4d	0.0202	0.0222
Long term	7d	0.0176	0.0209
	14d	0.0127	0.0187
	21d	0.0092	0.0175
	28d	0.0066	0.0160
	50d	0.0024	0.0122
	100d	0.0002	0.0070
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-9: PEC_{soil} for RH-24549 on vines

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0418	-
Short term	24h	0.0398	0.0408
	2d	0.0378	0.0398
	4d	0.0342	0.0379
Long term	7d	0.0294	0.0356
	14d	0.0207	0.0317
	21d	0.0146	0.0299
	28d	0.0102	0.0272
	50d	0.0034	0.0210
	100d	0.0003	0.0119
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-10: PEC_{soil} for RH-24549 on pome fruit

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0344	-
Short term	24h	0.0327	0.0335
	2d	0.0311	0.0327
	4d	0.0281	0.0312
Long term	7d	0.0242	0.0290
	14d	0.0170	0.0252
	21d	0.0120	0.0226
	28d	0.0084	0.0204
	50d	0.0028	0.0144
	100d	0.0002	0.0079
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-11: PEC_{soil} for RH-24549 on potatoes

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0362	-
Short term	24h	0.0344	0.0353
	2d	0.0327	0.0344
	4d	0.0296	0.0328
Long term	7d	0.0255	0.0309
	14d	0.0179	0.0277
	21d	0.0126	0.0257
	28d	0.0089	0.0232
	50d	0.0029	0.0176
	100d	0.0002	0.0099
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-12: PEC_{soil} for RH-163353 on vines

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0383	-
Short term	24h	0.0378	0.0380
	2d	0.0372	0.0378
	4d	0.0362	0.0372
Long term	7d	0.0347	0.0365
	14d	0.0315	0.0348
	21d	0.0286	0.0333
	28d	0.0259	0.0319
	50d	0.0191	0.0286
	100d	0.0095	0.0222
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-13: PEC_{soil} for RH-163353 on pome fruit

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0273	-
Short term	24h	0.0269	0.0271
	2d	0.0265	0.0269
	4d	0.0258	0.0265
Long term	7d	0.0247	0.0260
	14d	0.0224	0.0248
	21d	0.0204	0.0236
	28d	0.0185	0.0226
	50d	0.0136	0.0198
	100d	0.0068	0.0152
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-14: PEC_{soil} for RH-163353 on potatoes

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0323	-
Short term	24h	0.0319	0.0321
	2d	0.0314	0.0319
	4d	0.0306	0.0314
Long term	7d	0.0293	0.0308
	14d	0.0266	0.0294
	21d	0.0241	0.0281
	28d	0.0219	0.0269
	50d	0.0161	0.0240
	100d	0.0080	0.0186
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-15: PEC_{soil} for RH-141455 on vines

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0159	-
Short term	24h	0.0158	0.0158
	2d	0.0156	0.0158
	4d	0.0154	0.0156
Long term	7d	0.0150	0.0155
	14d	0.0142	0.0151
	21d	0.0135	0.0147
	28d	0.0128	0.0143
	50d	0.0107	0.0132
	100d	0.0073	0.0113
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-16: PEC_{soil} for RH-141455 on pome fruit

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0110	-
Short term	24h	0.0109	0.0110
	2d	0.0108	0.0109
	4d	0.0107	0.0108
Long term	7d	0.0104	0.0107
	14d	0.0099	0.0104
	21d	0.0093	0.0101
	28d	0.0088	0.0099
	50d	0.0074	0.0091
	100d	0.0050	0.0077
Plateau concentration (5 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.6-17: PEC_{soil} for RH-141455 on potatoes

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		0.0133	-
Short term	24h	0.0132	0.0133
	2d	0.0131	0.0132
	4d	0.0129	0.0131
Long term	7d	0.0126	0.0130
	14d	0.0120	0.0126
	21d	0.0113	0.0123
	28d	0.0107	0.0120
	50d	0.0090	0.0111
	100d	0.0061	0.0095
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

8.6.2.2 PEC_{soil} of Phosphonic acid considering the EU LoEP endpoints (SFO based DT_{50})

Table 8.6-18: PEC_{soil} for Phosphonic acid on vines

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		2.3337	-
Short term	24h	2.3254	2.3296
	2d	2.3172	2.3254
	4d	2.3009	2.3172
Long term	7d	2.2766	2.3050
	14d	2.2209	2.2768
	21d	2.1666	2.2491
	28d	2.1137	2.2219
	50d	1.9555	2.1390
	100d	1.6385	1.9686
Plateau concentration (5 cm)		0.8854	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		3.2191	-

Table 8.6-19: PEC_{soil} for Phosphonic acid on pome fruit

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		1.5832	-
Short term	24h	1.5776	1.5804
	2d	1.5720	1.5776
	4d	1.5610	1.5721
Long term	7d	1.5445	1.5638
	14d	1.5067	1.5447
	21d	1.4699	1.5258
	28d	1.4339	1.5073
	50d	1.3266	1.4511
	100d	1.1116	1.3342
Plateau concentration (5 cm)		0.6007	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		2.1839	-

Table 8.6-20: PEC_{soil} for Phosphonic acid on potatoes

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		1.9515	-
Short term	24h	1.9446	1.9481
	2d	1.9377	1.9446
	4d	1.9241	1.9378
Long term	7d	1.9038	1.9275
	14d	1.8572	1.9040
	21d	1.8118	1.8808
	28d	1.7675	1.8580
	50d	1.6352	1.7887
	100d	1.3702	1.6462
Plateau concentration (20 cm)		0.1851	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		2.1366	-

8.6.2.3 PEC_{soil} of Phosphonic acid considering dataset including LoEP (2013) for Disodium phosphate (DFOP based DT_{50})

Table 8.6-21: PEC_{soil} for Phosphonic acid on vines

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		2.1770	-
Short term	24h	2.1508	2.1639
	2d	2.1261	2.1512
	4d	2.0811	2.1272
Long term	7d	2.0229	2.0947
	14d	1.9193	2.0313
	21d	1.8457	1.9811
	28d	1.7900	1.9400
	50d	1.6680	1.8476
	100d	1.4679	1.7079
Plateau concentration (5 cm)		1.2800	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		3.4570	-

Table 8.6-22: PEC_{soil} for Phosphonic acid on pome fruit

PEC_{soil} (mg/kg)		Multiple application	
		Actual	TWA
Initial		1.5320	-
Short term	24h	1.5098	1.5209
	2d	1.4889	1.5101
	4d	1.4510	1.4899
Long term	7d	1.4023	1.4625
	14d	1.3172	1.4097
	21d	1.2585	1.3685
	28d	1.2157	1.3354
	50d	1.1272	1.2618
	100d	0.9907	1.1603
Plateau concentration (5 cm)		0.8638	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		2.3959	-

Table 8.6-23: PEC$_{soil}$ for Phosphonic acid on potatoes

PEC$_{soil}$ (mg/kg)		Multiple application	
		Actual	TWA
Initial		1.8303	-
Short term	24h	1.8075	1.8189
	2d	1.7862	1.8079
	4d	1.7472	1.7871
Long term	7d	1.6967	1.7589
	14d	1.6074	1.7041
	21d	1.5442	1.6608
	28d	1.4968	1.6256
	50d	1.3936	1.5467
	100d	1.2262	1.4284
Plateau concentration (20 cm)		0.2673	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		2.0976	-

8.6.2.4 PEC$_{soil}$ of formulation

PEC$_{soil}$ for the formulated product GWN-10616 were calculated assuming a soil density of 1.5 g/cm^3 and even distribution in the 0-5 cm layer. The maximum recommended rate to be applied is 1 x ~~4.275~~ 4.350 kg product/ha in vines, pome fruit and potatoes, considering a product density of ~~1.425~~ 1.45 kg/L. 60 % interception was assumed.

Table 8.6-24: PEC$_{soil}$ for formulation on crop

Active substance/ reparation	Application rate (g/ha)	PECact (mg/kg)	PEC$_{twa}$21 d (mg/kg)	Tillage depth (cm)	PECsoil,plateau (mg/kg)	PECaccu = PECact + PECsoil,plateau (mg/kg)
GWN-10616	~~1710~~ 1740	~~2.280~~ 2.320	n.c.	n.c.	n.c.	n.c.

8.7 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

The PEC of Zoxamide, its metabolites and Potassium phosphonates in groundwater has been assessed with standard FOCUS scenarios with the FOCUS models PELMO 6.6.4, PEARL 5.5.5 and MACRO 5.5.4.

Review Comments:

The PEC_{GW} calculations for zoxamide, its metabolites and for phosphonic acid were provided by the Applicant and are considered acceptable.

For active substances and relevant metabolites PEC_{GW} calculations were performed with FOCUS MACRO 5.5.4, FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. The EU agreed endpoints, including confirmatory data, were used. Geometric mean K_{foc} and K_{fom} (instead of an arithmetic mean K_{foc} and K_{fom}) for all compounds were derived from the datasets presented in the EFSA Journal 2017;15(9):4980 and EFSA Journal 2012;10(12):2963 for consistency with current FOCUS groundwater recommendation.

The leaching simulation run with FOCUS PELMO, FOCUS PEARL and FOCUS MACRO resulted in PEC_{GW} values below 0.1 µg/L for zoxamide and its metabolites RH-127450, RH-24549, and RH-163353, for all FOCUS scenarios.

Using refined endpoints, the metabolite RH-141455 exceed the threshold of 0.1 µg/L, but below 0.75 µg/L for all application uses. Maximum simulated concentrations of RH-141455 considering refined endpoints are 0.137 µg/L Châteaudun, 0.525 µg/L Hamburg, 0.506 µg/L Jokioinen, 0.367 µg/L Kremsmünster, 0.404 µg/L Okehampton, 0.286 µg/L Piacenza, 0.095 µg/L Porto calculated by model FOCUS PEARL 5.5.5 and 0.114 µg/L Châteaudun, 0.596 µg/L Hamburg, 0.157 µg/L Jokioinen, 0.581 µg/L Kremsmünster, 0.151 µg/L Okehampton, 0.279 µg/L Piacenza and 0.131 µg/L Porto calculated by model FOCUS PELMO 6.6.4. Therefore, the metabolite RH-141455 was subjected to a non-relevance assessment including a consumer exposure assessment according to the Guidance Document on the assessment of the relevance of metabolites in groundwater (see section Part B section 10). Based on this assessment metabolite RH-141455 is considered non-relevant with regard to groundwater for the proposed uses. It should be noted that in Applicant's calculations the formation fraction of 0.504 was used. Nevertheless, in RMS-LV opinion the correct ff value for the metabolite RH-141455 in Mechthildshausen soil is 1 and the correct arithmetic mean ff value is 0.629. Thus, during the comment stage the Applicant is requested to perform additional calculation for metabolite RH-141455 based on accepted by RMS-LV input parameters. These calculations are particularly required to confirm the maximum concentration of RH-141455 in groundwater below threshold of 0.75 µg/L, as assumed in the assessment of relevance of metabolites in part B10.

Additional calculations for metabolite RH-141455 based on accepted by RMS-LV input parameters were submitted by the Applicant. New PECgw values are consider to be valid. Maximum simulated concentrations of RH-141455 considering correct refined endpoints are 0.170 µg/L Châteaudun, 0.655 µg/L Hamburg, 0.632 µg/L Jokioinen, 0.235 µg/L Kremsmünster, 0.157 µg/L Okehampton, 0.356 µg/L Piacenza, 0.118 µg/L Porto calculated by model FOCUS PEARL 5.5.5 and 0.135 µg/L Châteaudun, 0.701 µg/L Hamburg, 0.636 µg/L Jokioinen, 0.338 µg/L Kremsmünster, 0.180 µg/L Okehampton, 0.341 µg/L Piacenza and 0.154 µg/L Porto calculated by model FOCUS PELMO 6.6.4.

All leaching simulation run with FOCUS PEARL resulted in PEC_{GW} values above 0.1 µg/L for phosphonic acid for all FOCUS scenarios. Maximum simulated concentrations of Phosphonic acid are 2.202 µg/L Châteaudun, 2.138 µg/L Hamburg, 4.629 µg/L Jokioinen, 3.764 µg/L Kremsmünster, 5.631 µg/L Okehampton, 0.904 µg/L Piacenza, 2.196 µg/L Porto and 0.481 µg/L Sevilla.

In compliance with the EFSA conclusions (EFSA Journal 2012; 10(12): 2963) on potassium phosphonates, all these groundwater concentrations are far below a health-based drinking water limit of 3 mg/L for phosphonic acid that was calculated following the WHO 2009 guideline.

8.7.1 Justification for new endpoints

For Zoxamide and metabolites RH-127450 and RH-163353 only EU agreed endpoints were used for the calculation of PEC_{gw}. For K_{foc}, the arithmetic mean is suggested for all substances in the EFSA conclusion (2017), while here the respective geometric mean values are used according to current EFSA guidelines (EFSA 2014).

EFSA conclusion (2017) set a geometric mean value of 5.4 days (n=4) for the metabolite RH-24549, which is not considering an additional soil degradation study (Derz, 2020) which has been performed with the Zoxamide metabolite RH-24549 to gather more detailed information on its degradation and the formation fraction (ff) values of its transformation product RH-141455 in three different soils under aerobic conditions in the dark. In the kinetic assessment study of Klein and Mendel-Kreusel (2020) those additional DT_{50} values for RH-24549 have been considered to calculate updated geometric mean $DegT_{50}$ value of 6.84 days (n=7) for RH-24549 and 7.48 days (n=7) for RH-141455. For the transformation of RH-24549 to RH-141455 an overall arithmetic mean formation fraction of 0.504 (n=4) was found. These values were used for groundwater simulations. Studies of Derz (2020) and Klein and Mendel-Kreusel (2020) were previously submitted to the RMS Latvia.

In RMS-LV opinion (available in Zoxamide_confirmatory_like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC) the correct ff value for the metabolite RH-141455 in Mechthildshausen soil is 1 and the correct arithmetic mean ff value is 0.629. Therefore, additional calculations for the metabolite RH-141455 were performed by the applicant and results are presented based on the input parameters accepted by RMS-LV.

According to the EFSA conclusion (EFSA Journal 2012; 10(12):2963) for Potassium phosphonates only Phosphonic acid is relevant for groundwater exposure assessment. Only EU agreed endpoints were used for the calculation of PEC_{gw} of Phosphonic acid.

8.7.2 Active substances and relevant metabolites (KCP 9.2.4.1)

Based on the EU review dossier (RAR 2017) and the EFSA Conclusion (2017) Zoxamide metabolites RH-127450, RH-24549, RH-163353 and RH-141455 are considered relevant for PEC_{gw} assessment.

According to the EFSA conclusion (2012), there are no metabolites of Phosphonic acid considered relevant for PEC_{gw} assessment.

Application dates were selected using the AppDate 3.06 according to the GAP. Details are indicated in Table 8.8-1 and Table 8.8.2.

Table 8.7-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1 covering 2	3 covering 4	5 covering 6
Crop	Grapevine	Pome fruit	Potatoes
FOCUS crop	*vines*	*apples*	*potatoes*
Growth stage	BBCH 14- 79	BBCH 51-69	BBCH 21-89
PHI	28	NR	7
Application rate (g as/ha)	Zoxamide: 180 Phosphonic acid: 1500	Zoxamide: 180 Phosphonic acid: 1500	Zoxamide: 150 Phosphonic acid: 1250
Number of applications/ interval (days)	3/8	2/6	3/7
Crop interception (%) Early: Late:	 60 75	 60 60	 60 85
Application rate (g as/ha) to the soil surface Zoxamide/ Phosphonic acid Early: Late:	 72/600 45/375	 72/600 72/600	 60/500 22.5/187.5
Frequency of application	Annual	Annual	Annual
Models used for calculation	FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5, FOCUS MACRO 5.5.4		

Table 8.7-2: Application dates selected for PEC_{gw} calculations

PEC_{gw} specific input values: application dates used for PEC_{gw} calculation in Grapevine treatment with early application at BBCH 14 and late application till BBCH 79

Scenario	Early application at BBCH 14			Late application till BBCH 79		
	1. Appl.	***2. Appl.***	***3. Appl.***	***1. Appl.***	***2. Appl.***	***3. Appl.***
Châteaudun	18/04	26/04	04/05	26/08	03/09	11/09
Hamburg	12/05	20/05	28/05	16/08	24/08	01/09
Jokioinen	-	-	-	-	-	-
Kremsmünster	12/05	20/05	28/05	16/08	24/08	01/09
Okehampton	-	-	-	-	-	-
Piacenza	18/04	26/04	04/05	26/08	03/09	11/09
Porto	03/04	11/04	19/04	11/08	19/08	27/08
Sevilla	11/04	19/04	27/04	14/08	22/08	30/08
Thiva	30/03	07/04	15/04	03/08	11/08	19/08
PEARL Project No.[*]	*ZOX_U1E* *KP_U1E*			*ZOX_U1L* *KP_U1L*		
PELMO Project No.[*]	*ZOX_U1E* *KP_U1E*			*ZOX_U1L* *KP_U1L*		

[*]For calculation with endpoints agreed by RMS Latvia "rFF" is used as a prefix for the Project No., for calculation considering purely EFSA conclusion endpoints "LoEP" is used as a prefix Project No.

PEC$_{gw}$ specific input values: application dates used for PEC$_{gw}$ calculation in multiple Pome fruit treatment with early application at BBCH 51 and late application till BBCH 69

Scenario	Early application at BBCH 51		Late application till BBCH 69	
	1. Appl.	**2. Appl.**	**1. Appl.**	**2. Appl.**
Châteaudun	03/05	09/05	24/05	30/05
Hamburg	26/05	01/06	23/06	29/06
Jokioinen	18/05	24/05	19/05	25/05
Kremsmünster	26/05	01/06	23/06	29/06
Okehampton	08/05	14/05	07/06	13/06
Piacenza	03/05	09/05	24/05	30/05
Porto	11/05	17/05	21/06	27/06
Sevilla	25/04	01/05	23/05	29/05
Thiva	11/05	17/05	21/06	27/06
PEARL Project No. *	*ZOX_U3E* *KP_U3E*		*ZOX_U3L* *KP_U3L*	
PELMO Project No. *	*ZOX_U3E* *KP_U3E*		*ZOX_U3L* *KP_U3L*	

*For calculation with endpoints agreed by RMS Latvia "rFF" is used as a prefix for the Project No., for calculation considering purely EFSA conclusion endpoints "LoEP" is used as a prefix Project No.

PEC$_{gw}$ specific input values: application dates used for PEC$_{gw}$ calculation in Potatoes treatment with early application at BBCH 21 and late application till BBCH 89

Scenario	Early application at BBCH 21			Late application till harvest – PHI*		
	1. Appl.	***2. Appl.***	***3. Appl.***	***1. Appl.***	***2. Appl.***	***3. Appl.***
Châteaudun	13/05/	20/05/	27/05/	11/08/	18/08/	25/08/
Hamburg	30/05/	06/06/	13/06/	25/08/	01/09/	08/09/
Jokioinen	29/06/	06/07/	13/07/	04/09/	11/09/	18/09/
Kremsmünster	30/05/	06/06/	13/06/	25/08/	01/09/	08/09/
Okehampton	22/05/	29/05/	05/06/	11/08/	18/08/	25/08/
Piacenza	02/05/	09/05/	16/05/	20/08/	27/08/	03/09/
Porto	06/04/	13/04/	20/04/	25/05/	01/06/	08/06/
Sevilla	17/02/	24/02/	03/03/	10/05/	17/05/	24/05/
Thiva	18/03/	25/03/	01/04/	09/07/	16/07/	23/07/
PEARL Project No. **	*ZOX_U10E* *KP_U10E*			*ZOX_U10L* *KP_U10L*		
PELMO Project No. **	*ZOX_U10E* *KP_U10E*			*ZOX_U10L* *KP_U10L*		

*Harvest-PHI occurs earlier then the latest relevant application dates for BBCH 89 by the AppDate 3.06

**For calculation with endpoints agreed by RMS Latvia "rFF" is used as a prefix for the Project No., for calculation considering purely EFSA conclusion endpoints "LoEP" is used as a prefix Project No.

PEC$_{gw}$ for Zoxamide and its metabolites are presented in Tables 8.8-7 to 8.8-25 and for Phosphonic acid are in Tables 8.8-28 to 8.8-30. Raw data to predicted environmental concentrations in groundwater for Zoxamide and its metabolites are summarised in Anonymous (2023), KCP 9.2.4.1/01 Doc. No. 782-005 and the updated calculations (with endpoints agreed by RMS Latvia) in Anonymous (2024), KCP 9.2.4.1/03 Doc. No. 782-029, and for Phosphonic acid in Anonymous (2023), KCP 9.2.4.1/02 Doc. No. 782-006.

Zoxamide and its metabolites

The PEC of Zoxamide and its metabolites in groundwater has been assessed with standard FOCUS scenarios with the FOCUS models PELMO 6.6.4 PEARL 5.5.5 and MACRO 5.5.4.

Calculations based exclusively on endpoints from List of endpoints are provided for the sake of completeness, followed by calculations based on current data set.

Table 8.7-3: Input parameters related to active substance Zoxamide for PEC_{gw} calculations

Parameter	Values	Remark/Reference
Molecular weight [g/mol]	336.65	EFSA conclusion (2017) [1)]
Water solubility [mg/L] (20 °C)	0.681	EFSA conclusion (2017) [1)]
Water solubility [mg/L] (25 °C)	0.820	Calculated from value at study temperature with Van´t Hoff equation
Vapour pressure [Pa] (20 °C)	$6.76x10^{-6}$	Calculated from value at study temperature with Van´t Hoff equation
Vapour pressure [Pa] (25 °C)	$1.3x10^{-5}$	EFSA conclusion (2017) [1)]
DT_{50} soil [d]	5.5 (geomean, n=6)	EFSA conclusion (2017) [1)]
Temperature correction function Reference temperature [°C]	20	FOCUS recommandation
Moisture correction function Reference moisture [-]	pF 2	FOCUS recommendation
Transformation rate [1/day]	0.126	Calculated from ln(2)/DT_{50}
Formation fractions [-] used in PEARL	0.24 to RH-127450 0.38 to RH-24549 0.18 to RH-163353	EFSA conclusion (2017) [1)]
Proportional transformation rates used in PELMO [1/day]	0.03025 to RH-127450 0.04789 to RH-24549 0.02268 to RH163353 0.02521 to CO_2	Calculated/ EFSA conclusion (2017) [1)]
K_{oc} [L/kg]	1179 (geomean, n=4)	EFSA conclusion (2017) [1)]
K_{om} [L/kg]	684	$K_{fom} = K_{foc} / 1.724$
Exponent of the Freundlich Isotherm 1/n [-]	0.970 (arithmetic mean, n=4)	EFSA conclusion (2017) [1)]
Plant uptake factor [-]	0	Worst case
Wash-off factor [m^{-1}]	100	Default, FOCUS recommandation
Half-life at crop surface [d]	10	Default, FOCUS recommandation

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980

Table 8.7-4: Input parameters related to active substance Zoxamide metabolites RH-127450, RH-24549, RH -163353 and RH-141455 for PEC_{gw} calculations

Parameter	RH-127450	RH-24549	RH-163353	RH-141455	Remark/Reference
Molecular weight [g/mol]	302.15	205.00	332.15	235.02	EFSA conclusion (2017) [1)]
Water solubility [mg/L]	1000	1000	1000	1000	Default, worst case
Vapour pressure [Pa] (20 °C)	0	0	0	0	Default, worst case
DT_{50} soil [d]	5.2 (n=5) [1)]	5.4 (n=5) [1)]	10.8 (n=4) [1)]	19.6 (n=4) [1)]	Geomean, EFSA conclusion (2017) [1)]
DT_{50} soil [d] refined	5.2 (n=5) [1)]	6.84 (n=7) [2,3)]	10.8 (n=4) [1)]	7.48 (n=7) [2,3)]	Geomean, EFSA conclusion (2017) [1)]/ Derz (2020) [2,3)]
Transformation rate [1/day]	0.13330	0.10134	0.06418	0.09267	Calculated from ln(2)/DT_{50}
Formation fractions [-] used in PEARL	0.24 from *Zoxamide* [1)]	0.38 from *Zoxamide* [1)]	0.18 from *Zoxamide* [1)]	1	EFSA conclusion (2017)
Formation fractions [-] used in PEARL refined	0.24 from *Zoxamide* [1)]	0.38 from *Zoxamide* [1)]	0.18 from *Zoxamide* [1)]	0.504 from RH-24549 [2,3)] 0.629 [8)]	EFSA conclusion (2017) [1)]/ Derz (2020) [2,3)]/[8)]
Proportional transformation rates [1/day] PELMO refined	0.13330 to CO_2	0.05107 and 0.06374[8)] to RH-141455 0.05026 and 0.03760[8)] to CO_2	0.06418 to CO_2	0.09267 to CO_2	Derived from ff and DT_{50}
Formation fractions [-] used in MACRO (all from Zoxamide) refined	0.24 [1)]	0.38 [1)]	0.18 [1)]	= 0.38 [1)]*0.504 [2,3)] = 0.1915 [4)] and = 0.38 [1)]*0.629 [8)] = 0.2390 [4)]	Calculated from EFSA conclusion (2017) [1)]/ Derz (2020) [2,3)] /[8)]
K_{oc} [mL/g]	593 (n=3)	90.55[5)] (n=3)	67 (n=3)	2.8 (n=3)	Geomean, EFSA conclusion (2017) [1)]
K_{om} [mL/g]	344	52.5 [5)]	39	1.6	$K_{om} = K_{oc}$ / 1.724
1/n [-]	0.9 [6)]	0.811	0.892	1.00 [7)]	EFSA conclusion (2017) [1)]
Plant uptake factor [-]	0	0	0	0	Worst case
Wash-off factor [m^{-1}]	100	100	100	100	Default, FOCUS recommandation
Half-life at crop surface [d]	10	10	10	10	Default, FOCUS recommandation

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] Derz, K. (2020). Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia
[3)] Klein, J., Mendel-Kreusel, R. (2020). Re-calculation of the degradation of RH-141455 and RH-24549 in soil based on the study data of Derz K. (2020): Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia
[4)] Macro cannot handle secondary metabolites. Therefore the formation fraction for MACRO was calculated as follows*: FF(zoxamide ->RH-141455) = FF(zoxamide -> RH24549) * FF (RH24549), i.e. = 0.38 * 0.504 = 0.1915 and with initial refinement of ff = 0.38 * 0.629 = 0.2390 when ff of RH-141455 as suggested by RMS-LV[8)] is used*
[5)] Worst case as adsorption pH dependent
[6)] The measured Freundlich exponent of 0.523 was considered unreliable so the default value was used
[7)] Adsorption of RH-141455 on soil was very low and therefore no desorption kinetics and adsorption/desorption isotherms were determined; hence a default value of 1 was used
[8)] In RMS-LV opinion the correct ff value for the metabolite RH-141455 in Mechthildshau-sen soil is 1 and the correct arithmetic mean ff value is **0.629**

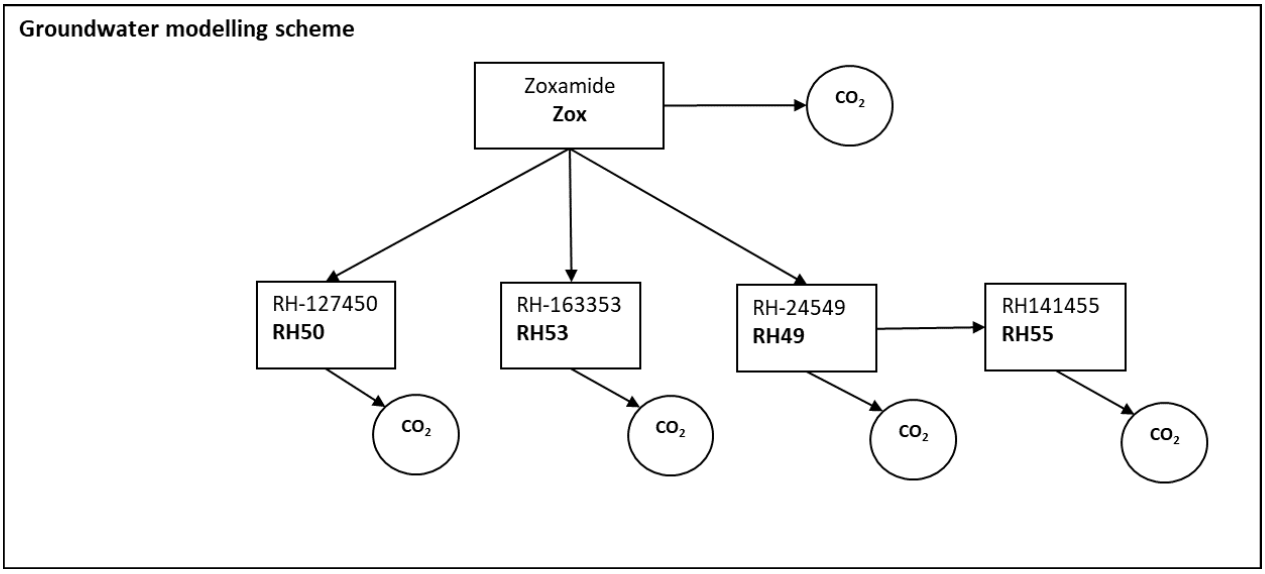


Table 8.7-5: Simplified degradations scheme used for groundwater modelling by PEARL 5.5.5 and PELMO 6.6.4

Table 8.7-6: PEC_{gw} specific input values: names and codes of substances used for modeling by FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 and FOCUS MACRO 5.5.4

Substance	Substance name PEARL*	Substance Code PEARL*	Substance Code PELMO
Zoxamide	Zoxamide	ZOX	See application dates table 8.8.-2*
RH-127450	RH-127450	RH50	
RH-24549	RH-24549	RH49	
RH-16353	RH-163353	RH53	
RH-141455	RH-141455	RH55	

*For calculation with endpoints agreed by RMS Latvia “rFF” is used as an annex for the substance code, for calculation considering purely EFSA conclusion endpoints “LoEP” is used as annex for substance codes.

PEC_{gw} calculated using the model FOCUS PEARL 5.5.5 based on LoEP endpoint

Table 8.7-7: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after <u>Grapevine</u> treatment at BBCH 14 with 3 x 0.180 kg a.s./ha based on LoEP endpoints

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	1.741	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	2.859	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	1.625	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.746	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.458	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.686	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.341	< 0.001

Table 8.7-8: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after <u>Grapevine</u> treatment until BBCH 79 with 3 x 0.180 kg a.s./ha based on LoEP endpoints

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	1.950	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	3.962	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	1.831	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	2.246	< 0.001
Porto	< 0.001	< 0.001	< 0.001	1.076	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.716	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.426	< 0.001

Table 8.7-9: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after <u>Pome fruit</u> treatment at BBCH 51 with 2 x 0.180 kg a.s./ha based on LoEP endpoints

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	1.797	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	5.002	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	1.555	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	4.434	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	1.279	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.593	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.360	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.679	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.911	< 0.001

Table 8.7-10: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Pome fruit treatment until BBCH 69 with 2 x 0.180 kg a.s./ha based on LoEP endpoints

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	1.686	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	6.567	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	4.462	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	1.720	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	1.334	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.608	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.532	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.746	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.938	< 0.001

Table 8.7-11: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Potatoes treatment at BBCH 21 with 3 x 0.150 kg a.s./ha based on LoEP endpoints

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	0.987	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	3.246	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	1.449	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	5.169	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	1.367	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.397	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.191	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.035	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.216	< 0.001

Table 8.7-12: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Potatoes treatment until BBCH 89 with 3 x 0.150 kg a.s./ha based on LoEP endpoints

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	0.633	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	2.469	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	0.956	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	2.131	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	1.183	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.936	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.052	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.018	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.192	< 0.001

PEC$_{gw}$ calculated using the model FOCUS PEARL 5.5.5 considering refined endpoints

Table 8.7-13: PEC$_{gw}$ at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Grapevine treatment at BBCH 14 with 3 x 0.180 kg a.s./ha

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-141455 rFF*	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	0.034	0.042	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	0.151	0.188	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	0.070	0.088	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.011	0.014	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.006	0.007	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.004	0.005	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.001	0.001	< 0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-14: PEC$_{gw}$ at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Grapevine treatment until BBCH 79 with 3 x 0.180 kg a.s./ha

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-141455 rFF*	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	0.137	0.170	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	0.509	0.635	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	0.188	0.235	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.286	0.356	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.095	0.118	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.016	0.020	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.006	0.007	< 0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-15: PEC$_{gw}$ at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Pome fruit treatment at BBCH 51 with 2 x 0.180 kg a.s./ha

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-141455 rFF*	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	0.037	0.046	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	0.395	0.493	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	0.057	0.071	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	0.261	0.325	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	0.049	0.061	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.006	0.008	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.004	0.005	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.003	0.009	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.008	0.003	< 0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-16: PEC$_{gw}$ at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Pome fruit treatment until BBCH 69 with 2 x 0.180 kg a.s./ha

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-141455 rFF*	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	0.038	0.047	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	0.525	0.655	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	~~0.072~~0.265	0.331	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	~~0.265~~0.072	0.090	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	0.056	0.070	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.006	0.007	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.010	0.012	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	0.005	0.012	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.010	0.006	< 0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-17: PEC$_{gw}$ at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Potatoes treatment at BBCH 21 with 3 x 0.150 kg a.s./ha

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-141455 rFF*	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	0.013	0.016	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	0.172	0.215	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	0.043	0.054	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	0.506	0.632	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	0.052	0.065	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.004	0.005	< 0.001
Porto	< 0.001	< 0.001	< 0.001	0.002	0.003	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-18: PEC$_{gw}$ at 1 m soil depth in µg/L (80th percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Potatoes treatment until BBCH 89 with 3 x 0.150 kg a.s./ha

Scenario	Zoxamide	RH-163353	RH-127450	RH-141455	RH-141455 rFF*	RH-24549
Châteaudun	< 0.001	< 0.001	< 0.001	0.029	0.036	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	~~0.126~~0.367	0.458	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	~~0.367~~0.126	0.129	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	~~0.103~~0.404	0.505	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	~~0.404~~0.103	0.157	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	0.091	0.114	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	<0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	<0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	0.005	0.006	< 0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

PEC_{gw} calculated using the model FOCUS PELMO 6.6.4

Table 8.7-19: PEC_{gw} at 1 m soil depth in µg/L (80^{th} percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PELMO 6.6.4 after Grapevine treatment at BBCH 14 with 3 x 0.180 kg a.s./ha

Scenario	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	RH-141455 rFF*
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	0.036	0.041
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	0.102	0.122
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	0.091	0.108
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	0.061	0.071
Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.030	0.035
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	0.002	0.003
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	0.001	0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-20: PEC_{gw} at 1 m soil depth in µg/L (80^{th} percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PELMO 6.6.4 after Grapevine treatment at BBCH 79 with 3 x 0.180 kg a.s./ha

Scenario	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	RH-141455 rFF*
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	0.114	0.135
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	0.596	0.701
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	0.279	0.338
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	0.279	0.341
Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.131	0.154
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	0.010	0.012
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	0.011	0.013

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-21: PEC_{gw} at 1 m soil depth in µg/L (80^{th} percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PELMO 6.6.4 after Pome fruit treatment at BBCH 51 with 2 x 0.180 kg a.s./ha

Scenario	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	RH-141455 rFF*
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	0.033	0.039
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	0.082	0.096
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	~~0.191~~0.065	0.078
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	~~0.065~~0.191	0.230
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	0.073	0.085
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	0.042	0.050
Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.008	0.009
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	0.003	0.003
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	0.002	0.002

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-22: PEC$_{gw}$ at 1 m soil depth in µg/L (80^{th} percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PELMO 6.6.4 after <u>Pome fruit</u> treatment at BBCH 69 with 2 x 0.180 kg a.s./ha

Scenario	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	RH-141455 rFF*
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	0.031	0.038
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	0.138	0.163
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	0.192	0.233
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	0.084	0.103
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	0.090	0.106
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	0.033	0.041
Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.009	0.011
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	0.003	0.004
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	0.004	0.005

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-23: PEC$_{gw}$ at 1 m soil depth in µg/L (80^{th} percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PELMO 6.6.4 after <u>Potatoes</u> treatment at BBCH 21 with 3 x 0.150 kg a.s./ha

Scenario	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	RH-141455 rFF*
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	0.011	0.013
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	0.099	0.112
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	~~0.529~~0.067	0.078
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	~~0.067~~0.529	0.636
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	0.073	0.085
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	0.009	0.01
Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.006	0.007
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	0.001	0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

Table 8.7-24: PEC$_{gw}$ at 1 m soil depth in µg/L (80^{th} percentile) for Zoxamide and its metabolites calculated with the leaching simulation model FOCUS PELMO 6.6.4 after <u>Potatoes</u> treatment at BBCH 89 with 3 x 0.150 kg a.s./ha

Scenario	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	RH-141455 rFF*
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	0.022	0.027
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	0.336	0.388
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	~~0.581~~0.157	0.183
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	~~0.157~~0.581	0.604
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	0.151	0.180
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	0.126	0.145
Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.003	0.004
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	0.001	0.001

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

PEC_{gw} calculated using the model MACRO 5.5.4

Table 8.7-25: PEC_{gw} for Zoxamide and its metabolites RH-127450, RH-24549, RH-163353 and RH-141455 for scenario Châteaudun (with MACRO 5.5.4)

Crop	Timing	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
	BBCH	**Zoxamide**	**RH-127450**	**RH-24549**	**RH-163353**	**RH-141455**	**RH-141455 rFF***
Grapevine	14	<0.001	<0.001	<0.001	<0.001	0.003	0.004
	Till 79	<0.001	<0.001	<0.001	<0.001	0.044	0.055
Pome fruit	51	<0.001	<0.001	<0.001	<0.001	0.001	0.002
	Till 69	<0.001	<0.001	<0.001	<0.001	0.001	0.001
Potatoes	21	<0.001	<0.001	<0.001	<0.001	0.003	0.003
	Till 89	<0.001	<0.001	<0.001	<0.001	0.009	0.012

*Calculation with metabolite RH-141455 based on the input parameters accepted by RMS-LV.

According to the results of the groundwater simulation FOCUS PEARL 5.5.5, FOCUS PELMO 6.6.4 and FOCUS MACRO 5.5.4 for active substance Zoxamide and its metabolites RH-127450, RH-24549, and RH- 163353 a groundwater contamination with concentration ≥ 0.1 µg/L can be excluded.

According to the results of the groundwater simulation FOCUS PEARL 5.5.5, FOCUS PELMO 6.6.4 and FOCUS MACRO 5.5.4 for active substance Zoxamide and its metabolites considering refined endpoints a groundwater contamination with concentration ≥ 0.1 µg/L cannot be excluded for metabolite RH-141455 for the assessed (critical) uses at FOCUS groundwater scenarios Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza and Porto. For the FOCUS groundwater scenarios Sevilla and Thiva a groundwater contamination with metabolite RH-141455 at concentrations ≥ 0.1 µg/L is not expected.

Maximum simulated concentrations of RH-141455 considering refined endpoints are ~~0.137~~0.170 µg/L Châteaudun, ~~0.525~~0.655 µg/L Hamburg, ~~0.506~~0.632 µg/L Jokioinen, ~~0.367~~0.235 µg/L Kremsmünster, ~~0.404~~0.157 µg/L Okehampton~~, 0.286~~0.356 µg/L Piacenza, ~~0.095~~0.118 µg/L Porto calculated by model FOCUS PEARL 5.5.5 and ~~0.114~~0.135 µg/L Châteaudun, ~~0.596~~0.701 µg/L Hamburg, ~~0.157~~0.636 µg/L Jokioinen, ~~0.581~~0.338 µg/L Kremsmünster, ~~0.151~~0.180 µg/L Okehampton, ~~0.279~~0.341 µg/L Piacenza and ~~0.131~~0.154 µg/L Porto calculated by model FOCUS PELMO 6.6.4.

Phosphonic acid

Table 8.7-26: Input parameters related to active substance Phosphonic acid for PEC_{gw} calculations

Compound	Phosphonic acid	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	80.5	Y [1)]
Water solubility (mg/L):	1875000 (25°C) 1557100 (20°C) [2)]	Y [1)]
Saturated vapour pressure (Pa):	0 (20°C) 0 (25°C)	Y [1)]
DT_{50} in soil (d) (lab)	196	Y [1)]
K_d (mL/g)	8.73	Y [1)] geomean
1/n	0.9	Y [1)]
Plant uptake factor	0	Default
Formation fraction	-	Y [1)]

[1)] EFSA conclusion on the peer review of the active substance Potassium phosphonates EFSA (2012)
[2)] In PEARL program limitation applies and maximum value of 1000000 mg/L is used for assessment

As the standard FOCUS model parameterizations are not designed for the simulation of the leaching of inorganic compounds, the applicant adapted the parameterization. Adsorption in the topsoil layer was implemented based on the K_d determined for the lowest concentration tested in the soil adsorption studies.

In compliance with the EFSA conclusion (2012) only results considering FOCUS PEARL (version 5.5.5) are provided within this submission.

For assessment with FOCUS PEARL 5.5.5, factors for adsorption down the soil profile are reduced, using the same reduction factors as implemented in the scenarios for reducing the transformation rates with increasing soil depth. The factor was 1 for up to 30 cm depth, 0.5 for the layer just below the plough layer (generally ca. 30 cm – 60 cm), 0.3 for the subsequent layer (generally 60 cm to 1 m) and 0.0 below 1 m depth. For each soil profile and horizon, the “Factors for Depth Effect” for sorption (*FacZSor*) were set accordingly. The factors for the effect of depth on transformation (*FacZTra*) remained unchanged for each soil horizon.

Table 8.7-27: Factors for adsorption down the soil profile for each crop-relevant FOCUS groundwater scenario in FOCUS PEARL 5.5.5

Horizon	*FacZsor*								
	Châteaudun	Hamburg	Jokioinen	Kremsm.	Okeham.	Piacenza	Porto	Sevilla	Thiva
1	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
2	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
3	0.5	0.5	0.5	0.5	0.5	0.5	1.0	1.0	0.5
4	0.5	0.3	0.3	0.5	0.5	0.5	0.5	0.5	0.5
5	0.5	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
6	0.3	0.3	0	0	0.3	0.3	0	0	0.3
7	0	0	0	0	0	0	0	0	0
8	0	0	0	-	0	0	-	0	0
9	0	-	-	-	-	-	-	-	-
10	0	-	-	-	-	-	-	-	-

PEC_{gw} calculated using the model FOCUS PEARL 5.5.5

Table 8.7-28: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Phosphonic acid calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Grapevine treatment at BBCH 14 and until BBCH 79 with 3 x 0.180 kg a.s./ha

Scenario	***BBCH 14***	***Till BBCH 79***
Châteaudun	2.202	1.110
Hamburg	2.138	1.145
Jokioinen	-	-
Kremsmünster	3.764	2.007
Okehampton	-	-
Piacenza	0.904	0.565
Porto	2.196	1.340
Sevilla	0.327	0.145
Thiva	0.009	0.003
PEARL Project No	KP_U1E	KP_U1L

Table 8.7-29: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Phosphonic acid calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Pome fruit treatment at BBCH 51 and until BBCH 69 with 2 x 0.180 kg a.s./ha

Scenario	***BBCH 51***	***Till BBCH 69***
Châteaudun	1.474	1.462
Hamburg	1.664	1.700
Jokioinen	4.623	4.629
Kremsmünster	2.257	2.274
Okehampton	4.490	4.519
Piacenza	0.493	0.498
Porto	1.704	1.893
Sevilla	0.481	0.458
Thiva	0.036	0.035
PEARL Project No	KP1_3UE	KP_3UL

Table 8.7-30: PEC_{gw} at 1 m soil depth in µg/L (80th percentile) for Phosphonic acid calculated with the leaching simulation model FOCUS PEARL 5.5.5 after Potatoes treatment at BBCH 21 and until BBCH 89 with 3 x 0.150 kg a.s./ha

Scenario	*BBCH 21*	*Till BBCH 89*
Châteaudun	0.319	0.029
Hamburg	1.265	0.183
Jokioinen	3.076	0.298
Kremsmünster	2.155	0.317
Okehampton	5.631	1.139
Piacenza	0.591	0.095
Porto	1.223	0.200
Sevilla	< 0.001	< 0.001
Thiva	< 0.001	< 0.001
PEARL Project No	KP_U10E	KP_U10L

According to the results of the groundwater simulation with Phosphonic acid using FOCUS PEARL 5.5.5 a concentration in groundwater ≥ 0.1 µg/L cannot be excluded for the assessed (critical) uses at FOCUS groundwater scenarios Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto and Sevilla. For the FOCUS groundwater scenarios Thiva a groundwater contamination at concentrations ≥ 0.1 µg/L is not expected.

Maximum simulated concentrations of Phosphonic acid are 2.202 µg/L Châteaudun, 2.138 µg/L Hamburg, 4.629 µg/L Jokioinen, 3.764 µg/L Kremsmünster, 5.631 µg/L Okehampton, 0.904 µg/L Piacenza, 2.196 µg/L Porto and 0.481 µg/L Sevilla.

In compliance with the EFSA conclusions (EFSA Journal 2012; 10(12): 2963) on Potassium phosphonates, all these groundwater concentrations are far below a health-based drinking water limit of 3 mg/L for Phosphonic acid that was calculated following the WHO 2009 guideline.

8.8 Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5)

Review Comments:

The $PEC_{SW/SED}$ calculations for zoxamide (Tier 1), its metabolites and for phosphonic acid were provided by the Applicant and are considered acceptable.

The EU agreed endpoints were used. Geometric mean K_{foc} and K_{fom} (instead of an arithmetic mean K_{foc} and K_{fom}) for all compounds were derived from the datasets presented in the EFSA Journal 2017;15(9):4980 and EFSA Journal 2012;10(12):2963 for consistency with current FOCUS groundwater recommendation.

For zoxamide, its relevant metabolites and for phosphonic acid PEC_{SW} calculations were performed with FOCUS STEPS 1-2 (active substances and relevant metabolites) and FOCUS STEP 3-4 (zoxamide).

zRMS agrees presented substance related input parameters (see Table 8.8-3) for zoxamide, except for refined half-life on crop canopy (DT50 on/in plants) values of 3.9 days. According to the conclusion of the RMS-LV evaluation, this value was not considered to be valid. The following information was taken from file: Zoxamide_confirmatory_like_data_Part_B5_B6_ B8_B9_ XXXX _LV_2023, Part B – Section 8, available on CIRCABC:

According to RMS calculations the appropriate modelling endpoint (DT50 on/in plants) for zoxamide for SW modelling purposes is 5.8 days, for more details please see RMS comments regarding Study 9 (KCP 9.2.5/06).

Thus, only FOCUS Step 3-4 PECsw values calculated using endpoints from LoEP (Tier 1) were considered to be acceptable to be used in the aquatic risk assessment.

With reference to zRMS request of July 2024, additional calculations of PECsw FOCUS Steps 3 - 4 for applications in potatoes were provided by the Applicant. The PECsw values performed with refined parameters were accepted by zRMS.

The PEC_{sw} reported below can be used for the risk assessment for aquatic organisms. Please refer to section 9.

8.8.1 Justification for new endpoints

For Zoxamide and its metabolites EU agreed endpoints were used for the calculation of PEC_{sw}, except K_{foc}, for which the respective geometric mean values are used according to Generic guidance for FOCUS surface water scenarios (version 1.4, May 2015).

From the soil degradation study of Burgener (1998) with the parent compound Zoxamide a formation fraction (ff) of 0.5 for RH-141455 developed from RH-24549 was determined but set to a default value of 1 (n=1) by EFSA (2017) (please refer to Volume 3 Part B. 8 of the final RAR for Zoxamide, 2017). The study of Derz (2020) with [^{14}C]-RH-24549 as test item investigated further its formation fraction and degradation behaviour. As a result, an overall arithmetic mean formation fraction of 0.504 (n=4) was found for the transformation of RH-24549 to RH-141455 together with an updated geometric mean $DegT_{50}$ value of 6.84 days (n=7) for RH-24549 and an overall geometric mean $DegT_{50}$ value of 7.48 days (n=7). These values were used for surface water simulations. ~~This study was previously submitted to the RMS Latvia~~.

However, in the RMS-LV opinion (available in Zoxamide_confirmatory_like_data_Part_B5_B6_ B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC) the correct ff value for the metabolite RH-141455 in Mechthildshausen soil is 1 and the correct arithmetic mean ff value is 0.629. This value was used for the updated surface water simulations for potatoes.

A geometric mean (n=32) foliar half-life of 3.9 days based on best-fit for Zoxamide based on residues data recently evaluated by Klein & Mendel-Kreusel (2020; re-port no. GOW1120-1) was initially considered for refined surface water simulations. This study was previously submitted to the RMS Latvia.

The degradation of Zoxamide on open-head salad varieties sprayed twice at nominally 180 g/ha with either Zoxium 240 SC (an SC formulation containing nominally 240 g/L Zoxamide) or GWN-9963 (SC formulation containing nominally 180 g/L of each Zoxamide and dimethomorph) at an interval of 8 ±1 days was studied in residues decline trials of Luciani (2012) in reports no. AGRI 013/12 GLP DEC and AGRI 014/12 GLP DEC. In total four decline trials were performed (in double) in season 2012 in the open field under Southern European growing conditions and four trials (in double) under greenhouse conditions. The studies on “open head” lettuce, rocket salad, endive and escarole were already evaluated and regarded valid by EFSA (2016) for the modification of maximum residue levels (MRLs) of Zoxamide in the crop groups ‘lettuces and salad plants’, ‘spinaches and similar leaves’ and ‘herbs and edible flowers’. As a result of a kinetic re-evaluation of the residues data, an overall geometric mean (n=16) foliar half-life of 4.2 days was derived for Zoxamide by Klein et al. (2020; report no. GOW1020-1); a summary of the document can be found in Appendix 2. In addition, the dissipation of Zoxamide on surrogate dicotyledonae (i.e. sugar beet leaves) and monocotyledonae (i.e. cereals) plants has been studied by Appeltauer (2020a,b,c,d) in the field under Northern and Southern European growing conditions, inclusive a kinetic evaluation of the degradation data. All available dissipation data of Zoxamide on plants were kinetically evaluated by Klein & Mendel-Kreusel (2020) in report no. GOW1120-1; a summary of the document can be found in Appendix 2. This study was previously submitted to the RMS Latvia. Based on their evaluation results, Klein & Mendel-Kreusel (2020) proposed a geometric mean (n=32) foliar half-life of 3.9 d based on best-fit Zoxamide residues data.

In accordance with the conclusion of RMS Latvia assessment of the Klein & Mendel-Kreusel (2020) study, RMS Poland considers the DT_{50} on/in plants of 5.8 days for Zoxamide as the appropriate modelling endpoint for surface water modelling purposes. For this reason, RMS Poland considered FOCUS Step 3-4 PEC_{sw} values calculated using foliar half-life of 3.9 days as non-acceptable and used FOCUS Step 3-4 PEC_{sw} values calculated using LoEP (Tier 1) endpoints in the aquatic risk assessment, demonstrating safe use of Zoxamide on grapevine and pome fruit as suggested by the applicant together with single use on potatoes (for details please refer to the part B9). To demonstrate that the multiple application on potatoes is also safe, an additional FOCUS Step3-4 calculation considering the refined foliar DT_{50} of 5.8 days is presented below.

Only EU agreed endpoints were used for the calculation of PEC_{sw} of for Potassium phosphonates.

8.8.2 Active substances, relevant metabolites and the formulation (KCP 9.2.5)

According to the residue definition given in the EFSA conclusion (EFSA Journal 2017; 15(9):4980) Zoxamide and its metabolites RH-127450, RH-24549, RH-163353, RH-141455 and RH-139432 are considered to be of relevance for surface water and sediment exposure assessment.

According to the EFSA conclusion (EFSA Journal 2012; 10(12):2963) Phosphonic acid and Phosphate as the only relevant metabolite are considered relevant for surface water and sediment exposure assessment of Potassium phosphonates. Application rate of Phosphate ions was determined based on the molar basis.

The PEC of Zoxamide and its metabolites and Phosphonic acid and Phosphate ions in surface water and sediment have been assessed with standard FOCUS scenarios following the stepwise exposure assessment (Step 1 – Step 4) as indicated in the Table 8.9.1

Raw data to predicted environmental concentrations in surface water for Zoxamide are included in Anonymous (2023), KCP 9.2.5/01, Doc. No. 782-007 and the updated calculations on potatoes (with endpoints agreed by RMS Latvia) in Anonymous (2024), KCP 9.2.5/03, Doc. No. 782-030. Raw data to predicted environmental concentrations in surface water for Phosphonic acid are included in Anonymous (2023), KCP 9.2.5/02, Doc. No. 782-008.

Table 8.8-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Use No.	1 covering 2	3 covering 4	5 covering 6
Crop	Grapevine	Pome fruit	Potatoes
FOCUS crop	*Vines late applications*	*Pome/stonefruit early applications*	*Potatoes*
Growth stage	14-79	51-69	21-89
PHI	28	-	7
Application rate (g as/ha)	Zoxamide: 180 Phosphonic acid: 1500	Zoxamide: 180 Phosphonic acid: 1500	Zoxamide: 150 Phosphonic acid: 1250
Number of applications/interval (days)	3/8	2/6	3/7
Application window (Step 1 and 2)	SE and NE March-May, June –Sep	SE and NE March-May, June –Sep	SE and NE March-May, June –Sep
Application method	foliar spray	foliar spray	foliar spray
CAM/DEPI	2/4	2/4	2/4
Model to be used	FOCUS STEP1-4	FOCUS STEP1-4	FOCUS STEP1-4

Application windows were selected via the tool AppDate version 3.06 according to the GAP. Details are indicated in Table 8.9-1 and Table 8.9-2.

Table 8.8-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of GWN 10616

Application windows used for $PEC_{sw/sed}$ STEP 3 and STEP4 calculations considering Grapevine treatment between BBCH 14 and BBCH 79

Multiple treatment			
FOCUS Crop	**Scenario**	**Water body type**	**Application window**
BBCH 14			
Vines	D6 (Thiva)	Ditch	14/02 – 01/04
	R1 (Weiherbach)	Pond, Stream	26/04 – 11/06
	R2 (Porto)	Stream	03/04 – 19/05
	R3 (Bologna)	Stream	18/04 – 03/06
	R4 (Roujan)	Stream	28/03 – 13/05
BBCH 79			
Vines	D6 (Thiva)	Ditch	11/06 – 27/07
	R1 (Weiherbach)	Pond, Stream	09/07 – 24/08
	R2 (Porto)	Stream	12/07 – 27/08
	R3 (Bologna)	Stream	27/07 – 11/09
	R4 (Roujan)	Stream	02/07 – 17/08

Single treatment			
FOCUS Crop	**Scenario**	**Water body type**	**Application window**
BBCH 14			
Vines	D6 (Thiva)	Ditch	14/02 – 16/03
	R1 (Weiherbach)	Pond, Stream	26/04 – 26/05
	R2 (Porto)	Stream	03/04 – 03/05
	R3 (Bologna)	Stream	18/04 – 18/05
	R4 (Roujan)	Stream	28/03 – 27/04
BBCH 79			
Vines	D6 (Thiva)	Ditch	27/06 – 27/07
	R1 (Weiherbach)	Pond, Stream	25/07 – 24/08
	R2 (Porto)	Stream	28/07 – 27/08
	R3 (Bologna)	Stream	12/08 – 11/09
	R4 (Roujan)	Stream	18/07 – 17/08

Application windows used for $PEC_{sw/sed}$ STEP 3 and STEP4 calculations considering Pome fruit treatment between BBCH 51 and BBCH 69

Multiple treatment			
FOCUS Crop	**Scenario**	**Water body type**	**Application window**
BBCH 51			
Pome/stone fruit	D3 (Vreedepeel)	Ditch	25/05 – 01/07
	D4 (Skousbo)	Pond, Stream	30/05 – 05/07
	D5 (La Jailliere)	Pond, Stream	03/05 – 08/06
	R1 (Weiherbach)	Pond, Stream	26/05 – 01/07
	R2 (Porto)	Stream	27/05 – 02/07
	R3 (Bologna)	Stream	03/05 – 08/06
	R4 (Roujan)	Stream	25/04 – 31/05
BBCH 69			
Pome/stone fruit	D3 (Vreedepeel)	Ditch	24/05 – 29/06
	D4 (Skousbo)	Pond, Stream	28/05 – 03/07
	D5 (La Jailliere)	Pond, Stream	24/04 – 30/05
	R1 (Weiherbach)	Pond, Stream	24/05 – 29/06
	R2 (Porto)	Stream	22/06 – 28/07
	R3 (Bologna)	Stream	24/04 – 30/05
	R4 (Roujan)	Stream	23/04 – 29/05

Single treatment			
FOCUS Crop	**Scenario**	**Water body type**	**Application window**
BBCH 51			
Pome/stone fruit	D3 (Vreedepeel)	Ditch	26/05 – 25/06
	D4 (Skousbo)	Pond, Stream	30/05 – 29/06
	D5 (La Jailliere)	Pond, Stream	03/05 – 02/06
	R1 (Weiherbach)	Pond, Stream	26/05 – 25/06
	R2 (Porto)	Stream	27/05 – 26/06
	R3 (Bologna)	Stream	03/05 – 02/06
	R4 (Roujan)	Stream	25/04 – 25/05
BBCH 69			
Pome/stone fruit	D3 (Vreedepeel)	Ditch	30/05 – 29/06
	D4 (Skousbo)	Pond, Stream	03/06 – 03/07
	D5 (La Jailliere)	Pond, Stream	30/04 – 30/05
	R1 (Weiherbach)	Pond, Stream	30/05 – 29/06
	R2 (Porto)	Stream	28/06 – 28/07
	R3 (Bologna)	Stream	30/04 – 30/05
	R4 (Roujan)	Stream	29/04 – 29/05

Application windows used for STEP 3 and STEP 4 calculations considering Potatoes treatment between BBCH 21 and BBCH 89 (harvest – PHI)

Multiple treatment			
FOCUS Crop	**Scenario**	**Water body type**	**Application window**
BBCH 21			
Potatoes	D3 (Vreedepeel)	Ditch	30/05 – 13/07
	D4 (Skousbo)	Pond, Stream	17/06 – 31/07
	D6 (Thiva)	Ditch 1st crop	24/04 – 07/06*
	D6 (Thiva)	Ditch 2nd crop	21/08 – 04/10*
	R1 (Weiherbach)	Pond, Stream	20/05 – 03/07
	R2 (Porto)	Stream	06/04 – 20/05
	R3 (Bologna)	Stream	24/04 – 07/06
BBCH 89			
Potatoes	D3 (Vreedepeel)	Ditch	26/07 – 08/09
	D4 (Skousbo)	Pond, Stream	03/08 – 16/09
	D6 (Thiva)	Ditch 1st crop	25/05 – 08/07*
	D6 (Thiva)	Ditch 2nd crop	05/10 – 18/11*
	R1 (Weiherbach)	Pond, Stream	19/07 – 01/09
	R2 (Porto)	Stream	25/04 – 08/06
	R3 (Bologna)	Stream	12/07 – 25/08

* Not relevant for CEZ

Single treatment			
FOCUS Crop	**Scenario**	**Water body type**	**Application window**
BBCH 21			
Potatoes	D3 (Vreedepeel)	Ditch	30/05 – 29/06
	D4 (Skousbo)	Pond, Stream	17/06 – 17/07
	D6 (Thiva)	Ditch 1st crop	24/04 – 24/05*
	D6 (Thiva)	Ditch 2nd crop	21/08 – 20/09*
	R1 (Weiherbach)	Pond, Stream	20/05 – 19/06
	R2 (Porto)	Stream	06/04 – 06/05
	R3 (Bologna)	Stream	24/04 – 24/05
BBCH 89			
Potatoes	D3 (Vreedepeel)	Ditch	09/08 – 08/09
	D4 (Skousbo)	Pond, Stream	17/08 – 16/09
	D6 (Thiva)	Ditch 1st crop	08/06 – 08/07*
	D6 (Thiva)	Ditch 2nd crop	19/10 – 18/11*
	R1 (Weiherbach)	Pond, Stream	02/08 – 01/09
	R2 (Porto)	Stream	09/05 – 08/06
	R3 (Bologna)	Stream	26/07 – 25/08

* Not relevant for CEZ

Zoxamide and its metabolites

Table 8.8-3: Input parameters related to active substance Zoxamide for $PEC_{sw/sed}$ calculations STEP 1/2 and 3/4

Parameter	**Value**	**Remark/Reference**
Molecular weight [g/mol]	336.65	EFSA conclusion (2017) [1)]
Water solubility [mg/L] (20°C)	0.681	EFSA conclusion (2017) [1)]
Vapour pressure [Pa] (25°C)	$1.3x10^{-5}$	EFSA conclusion (2017) [1)]
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	Default
Diffusion coefficient in air (m²/d)	0.43	Default
K_{oc} [L/kg]	1179 (geomean, n=4)	EFSA conclusion (2017) [1)]
K_{om} [L/kg]	684	$K_{om} = K_{oc} / 1.724$
Exponent of the Freund-lich Isotherm 1/n [-]	0.970 (arithmetic mean, n=4)	EFSA conclusion (2017) [1)]
DT_{50} soil [d]	5.5 (geomean, n=6)	EFSA conclusion (2017) [1)]
DT_{50} water [d]*	1000 [2)]/6.4 [1)]	worst-case default/ EFSA conclusion (2017) [1)]
DT_{50} sediment [d]*	6.4 [1)]/1000 [2)]	EFSA conclusion (2017) [1)]/worst case default [2)]
DT_{50} water/sediment [d]	6.4 (arithmetic mean, n=2)	EFSA conclusion (2017) [1)]
Half-life on crop canopy (d)	10	Default
Half-life on crop canopy refined (d)	5.8~~3.9~~ [3)]	~~Klein, J. and Mendel-Kreusel, R. (2020)~~ Zoxamide_confirmatory_like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8[3)]

Max. occurrence in soil [%]:	-	-
Max. occurrence in water/sediment system [%]	-	-
Formation fraction in soil:	-	-
Temperature correction function Reference temperature [°C] TOXSWA: activation energy [J mol-1]	20 65 400	FOCUS recommendation EFSA recommendation
Crop uptake factor [-]	0	FOCUS recommendation for non-systemic compounds
Wash off coefficient from crop[m^{-1}]	50	Default, FOCUS recommendation
Temperature correction function Reference temperature [°C] MACRO: [K-1] PRZM: Q10 [-]	20 0.095 2.58	FOCUS recommendation EFSA recommendation EFSA recommendation
Moisture correction function Reference moisture [-] PRZM / MACRO: moisture exponent [-]	pF 2 0.70 (Walker) / 0.49 (calibrated value)	FOCUS recommendation

[1)] EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
[2)] Worst case default in absence of measured value
[3)] ~~Klein, J., Mendel-Kreusel, R. (2020): Residue dissipation of Zoxamide on/in plants, Report No. GOW1120-1. This study was previously submitted to the RMS Latvia~~ Zoxamide_confirmatory_like_data_Part_B5_B6_ B8_B9_XXXX_LV_2023, Part B – Section 8
[*]The combination $DegT_{50}$ in sediment = 6.4 d and $DegT_{50}$ in water = 1000 d was found to be the worst-case for PEC_{sw} in most of the scenarios (see EFSA, 2017), the alternative combination ($DegT_{50}$ of 6.4 days in water, $DegT_{50}$ of 1000 days in sediment) was therefore not considered further.

Review Comments:

zRMS agrees presented substance related input parameters (see Table 8.8-3) for zoxamide, except for refined half-life on crop canopy (DT50 on/in plants) values of 3.9 days. According to the conclusion of the RMS-LV evaluation, this value was not considered to be valid. The following information was taken from file: Zoxamide_confirmatory_like_data_Part_B5_B6_ B8_B9_ XXXX _LV_2023, Part B – Section 8, available on CIRCABC:

According to RMS calculations the appropriate modelling endpoint (DT50 on/in plants) for zoxamide for SW modelling purposes is 5.8 days, for more details please see RMS comments regarding Study 9 (KCP 9.2.5/06).

Thus, only FOCUS Step 3-4 PECsw values calculated using endpoints from LoEP (Tier 1) were considered to be acceptable to be used in the aquatic risk assessment.

Table 8.8-4: Input parameters related to active substance Zoxamide metabolites RH-127450, RH-24549, RH -163353, RH-141455 and RH-139432 for $PEC_{sw/sed}$ calculations STEP 1/2

Parameter	RH-127450	RH-24549	RH-163353	RH-141455	RH-139432	Remark/Reference
Molecular weight [g/mol]	302.15	205.00	332.15	235.02	204.06	EFSA conclusion (2017) [1)]
Water solubility [mg/L]	1000	1000	1000	1000	1000	Default, worst case
K_{oc} [mL/g]	593 (n=3)	90.55 [3)] (n=3)	67 (n=3)	2.8 (n=3)	10 [2)]	Geomean, EFSA conclusion (2017) [1)]/ [2)]
K_{om} [mL/g]	344	52.5 [3)]	39	1.6	5.77 [2)]	$K_{om} = K_{oc}$ / 1.724
1/n [-]	0.9[4)]	0.811	0.892	1.00[5)]	-	EFSA conclusion (2017) [1)] / [4),5)]
DT_{50} soil [d]	5.2 (n=5) [1)]	5.4 (n=5) [1)]	10.8 (n=4) [1)]	19.6 (n=4) [1)]	1000 [2)]	Geomean, EFSA conclusion (2017) [1)]~~/ Derz (2020) [6,7)]~~
DT_{50} soil [d] refined	5.2 (n=5) [1)]	6.84 (n=7) [6,7)]	10.8 (n=4) [1)]	7.48 (n=7) [6,7)]	1000	Geomean, EFSA conclusion (2017) [1)]/ Derz (2020) [6,7)]
DT_{50} water [d]	237 [8)]	1000	1000	1000	1000	Default, worst case
DT_{50} sediment [d]	237 [8)]	1000	1000	1000	1000	Default, worst case
DT_{50} water/sediment [d]	237 [8)]	1000	1000	1000	1000	Default, worst case
Max. occurrence in soil [%]:	15.1	33.8	15	8.4	4.9	EFSA conclusion (2017)[1)]
Max. occurrence in water/sediment system [%]	39.3 [1,9)]	5	20.6	2.1	21.4 [10)]	Geomean, EFSA conclusion (2017) [1)]/[10)]

1) EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance Zoxamide. EFSA Journal 2017, 5 (9):4980
2) Worst case default in absence of measured value
3) Worst case as adsorption pH dependent
4) The measured Freundlich exponent of 0.523 was considered unreliable so the default value was used
5) Adsorption of RH-141455 on soil was very low and therefore no desorption kinetics and adsorption/desorption isotherms were determined; hence a default value of 1 was used
6) Derz, K. (2020). Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia
7) Klein, J., Mendel-Kreusel, R. (2020). Re-calculation of the degradation of RH-141455 and RH-24549 in soil based on the study data of Derz K. (2020): Aerobic degradation of RH-24549 in three soils. This study was previously submitted to the RMS Latvia
8) Following the Generic guidance for FOCUS surface water Scenarios (2015) and SANCO/10058/2005, DT_{50} whole system must be assigned to both compartments in STEP 2
9) As the worst-case scenario, the higher value obtained when the system was incubated at 10°C is used for the simulations
10) This metabolite appears at a max. of 21.4 % in surface water in an OECD 309 study (EFSA 2017). It appears at max. of 42.4 % AR in an aquatic photolysis study with the parent compound, performed at pH 4. However, a pH of 4 is not environmentally relevant.

Review Comments:

zRMS agrees presented substance related input parameters (see Table 8.8-4) for zoxamide metabolites. Thus, FOCUS Step 1-2 PECsw values were considered to be acceptable to be used in the aquatic risk assessment.

The confirmatory-like study by Derz, 2020, was evaluated and accepted by the RMS-LV for zoxamide in an interzonal procedure. All details are to be found in the file: Zoxamide_confirmatory_like_data_Part_B5_B6_B8_B9_ XXXX _LV_2023, Part B – Section 8, available on CIRCABC.

FOCUS STEP 1 and 2 for Zoxamide

Table 8.8-5: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		84.4	30.0	825.1
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	4.8	2.6	34.1
	June - Sep.	minimal (40 %)	4.8	2.6	34.1
South Europe	Mar. - May	minimal (40 %)	5.4	2.9	54.0
	June - Sep.	minimal (40 %)	4.8	2.7	44.0
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	6.5	3.7	55.7
	June - Sep.	minimal (40 %)	6.5	3.7	55.7
South Europe	Mar. - May	minimal (40 %)	8.7	4.5	84.9
	June - Sep.	minimal (40 %)	7.5	3.8	70.0

Table 8.8-6: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		84.4	30.0	825.1
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	4.8	1.9	28.1
	June - Sep.	full canopy (60 %)	4.8	1.9	28.1
South Europe	Mar. - May	full canopy (60 %)	4.8	2.6	40.7
	June - Sep.	full canopy (60 %)	4.8	2.2	34.1
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	6.5	3.2	46.8
	June - Sep.	full canopy (60 %)	6.5	3.2	46.8
South Europe	Mar. - May	full canopy (60 %)	7.1	3.6	65.0
	June - Sep.	full canopy (60 %)	6.5	3.7	55.7

Table 8.8-7: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to pome fruit with application rate 180 g/ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		81.7	24.3	550.1
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	17.5	5.4	69.4
	June - Sep.	full canopy (65 %)	17.5	5.4	69.4
South Europe	Mar. - May	full canopy (65 %)	17.5	5.9	79.8
	June - Sep.	full canopy (65 %)	17.5	5.6	74.6
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	21.2	7.9	104.2
	June - Sep.	full canopy (65 %)	21.2	7.8	104.2
South Europe	Mar. - May	full canopy (65 %)	21.2	8.7	119.6
	June - Sep.	full canopy (65 %)	21.2	8.3	111.9

Table 8.8-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		62.5	23.7	687.6
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	1.8	0.9	17.8
	June - Sep.	average (50 %)	1.8	0.9	17.8
South Europe	Mar. - May	average (50 %)	2.9	1.6	31.7
	June - Sep.	average (50 %)	2.4	1.3	24.8
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	2.8	1.5	28.3
	June - Sep.	average (50 %)	2.8	1.2	28.3
South Europe	Mar. - May	average (50 %)	4.7	2.6	50.3
	June - Sep.	average (50 %)	3.7	2.0	39.3

Table 8.8-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		62.5	23.7	687.6
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	1.4	0.8	12.3
	June - Sep.	full canopy (70 %)	1.4	0.8	12.3
South Europe	Mar. - May	full canopy (70 %)	2.0	1.1	20.7
	June - Sep.	full canopy (70 %)	1.6	0.9	16.5
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	2.1	1.1	19.6
	June - Sep.	full canopy (70 %)	2.1	1.1	19.6
South Europe	Mar. - May	full canopy (70 %)	3.2	1.7	32.7
	June - Sep.	full canopy (70 %)	2.6	1.4	26.2

FOCUS Step 3 for Zoxamide considering endpoints based on LoEP

Table 8.8-10: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to vines at application rate of 3 x 180 g a.s./ha, at BBCH 14 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D6	Ditch	2.638	Spray-drift	2.754
R1	Pond	0.235	Spray-drift	0.626
R1	Stream	1.911	Spray-drift	0.410
R2	Stream	2.577	Spray-drift	0.219
R3	Stream	2.719	Spray-drift	0.656
R4	Stream	1.911	Spray-drift	1.597

Table 8.8-11: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to vines at application rate of 1 x 180 g a.s./ha, at BBCH 14 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D6	Ditch	3.026	Spray-drift	0.822
R1	Pond	0.110	Spray-drift	0.254
R1	Stream	2.242	Spray-drift	0.255
R2	Stream	2.979	Spray-drift	0.178
R3	Stream	3.172	Spray-drift	0.612
R4	Stream	2.242	Spray-drift	0.253

Table 8.8-12: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to vines at application rate of 3 x 180 g a.s./ha, till BBCH 79 based on LoEP endpoints

Scenario FOCUS	Waterbody		Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3					
D6	Ditch		3.625	Spray-drift	4.655
R1	Pond		0.201	Spray-drift	0.460
R1	Stream		1.929	Spray-drift	0.281
R2	Stream		2.586	Spray-drift	0.218
R3	Stream		2.720	Spray-drift	0.755
R4	Stream		1.929	Spray-drift	0.596

Table 8.8-13: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to vines at application rate of 1 x 180 g a.s./ha, till BBCH 79 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D6	Ditch	3.086	Spray-drift	3.360
R1	Pond	0.110	Spray-drift	0.213
R1	Stream	2.202	Spray-drift	0.173
R2	Stream	3.034	Spray-drift	0.231
R3	Stream	3.191	Spray-drift	0.715
R4	Stream	2.263	Spray-drift	0.318

Table 8.8-14: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to pome fruit at application rate of 2 x 180 g a.s./ha, at BBCH 51 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	12.050	Spray-drift	7.687
D4	Pond	1.210	Spray-drift	2.574
D4	Stream	12.680	Spray-drift	2.238
D5	Pond	1.335	Spray-drift	2.996
D5	Stream	13.690	Spray-drift	3.184
R1	Pond	1.335	Spray-drift	2.859
R1	Stream	9.700	Spray-drift	1.396
R2	Stream	13.000	Spray-drift	1.117
R3	Stream	13.690	Spray-drift	3.273
R4	Stream	9.697	Spray-drift	1.320

Table 8.8-15: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to pome fruit at application rate of 1 x 180 g a.s./ha, at BBCH 51 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	14.010	Spray-drift	8.765
D4	Pond	0.849	Spray-drift	1.800
D4	Stream	14.240	Spray-drift	1.095
D5	Pond	0.849	Spray-drift	1.862
D5	Stream	15.180	Spray-drift	1.067
R1	Pond	0.849	Spray-drift	1.688
R1	Stream	11.360	Spray-drift	1.551
R2	Stream	15.220	Spray-drift	1.129
R3	Stream	15.930	Spray-drift	2.917
R4	Stream	11.360	Spray-drift	1.546

Table 8.8-16: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to pome fruit at application rate of 2 x 180 g a.s./ha, till BBCH 69 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	12.050	Spray-drift	7.673
D4	Pond	1.403	Spray-drift	3.113
D4	Stream	12.290	Spray-drift	1.289
D5	Pond	1.329	Spray-drift	3.146
D5	Stream	12.950	Spray-drift	0.960
R1	Pond	1.335	Spray-drift	2.859
R1	Stream	9.700	Spray-drift	1.396
R2	Stream	13.020	Spray-drift	1.106
R3	Stream	13.640	Spray-drift	2.757
R4	Stream	9.697	Spray-drift	1.320

Table 8.8-17: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to pome fruit at application rate of 1 x 180 g a.s./ha, till BBCH 69 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	14.010	Spray-drift	8.765
D4	Pond	0.849	Spray-drift	1.802
D4	Stream	14.340	Spray-drift	1.232
D5	Pond	0.849	Spray-drift	1.862
D5	Stream	15.180	Spray-drift	1.067
R1	Pond	0.849	Spray-drift	1.688
R1	Stream	11.360	Spray-drift	1.551
R2	Stream	15.250	Spray-drift	1.156
R3	Stream	15.930	Spray-drift	2.917
R4	Stream	11.120	Spray-drift	0.954

Table 8.8-18: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, at BBCH 21 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.571	Spray-drift	0.306
D4	Pond	0.059	Spray-drift	0.126
D4	Stream	0.459	Spray-drift	0.019
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.104	Spray-drift	0.233
R1	Stream	0.800	Run-off	0.924
R2	Stream	0.529	Spray-drift	0.450
R3	Stream	0.862	Run-off	0.444

* Not relevant for CEZ

Table 8.8-19: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, at BBCH 21 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.786	Spray-drift	0.372
D4	Pond	0.032	Spray-drift	0.063
D4	Stream	0.614	Spray-drift	0.018
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.066	Run-off	0.147
R1	Stream	0.605	Run-off	0.756
R2	Stream	0.719	Spray-drift	0.107
R3	Stream	0.767	Spray-drift	0.167

* Not relevant for CEZ

Table 8.8-20: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, till BBCH 89 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.572	Spray-drift	0.334
D4	Pond	0.058	Spray-drift	0.154
D4	Stream	0.482	Spray-drift	0.032
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.051	Spray-drift	0.119
R1	Stream	0.394	Spray-drift	0.058
R2	Stream	0.529	Spray-drift	0.743
R3	Stream	0.716	Run-off	1.113

* Not relevant for CEZ

Table 8.8-21: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, till BBCH 89 based on LoEP endpoints

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.787	Spray-drift	0.426
D4	Pond	0.032	Spray-drift	0.071
D4	Stream	0.591	Spray-drift	0.015
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.032	Spray-drift	0.067
R1	Stream	0.545	Spray-drift	0.078
R2	Stream	0.731	Spray-drift	0.223
R3	Stream	0.768	Spray-drift	0.681

* Not relevant for CEZ

FOCUS Step 3 for Zoxamide considering the half-life on crop canopy of 5.8 days

Table 8.8-22: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, at BBCH 21 considering the half-life on crop canopy of 5.8 days

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.571	Spray-drift	0.306
D4	Pond	0.059	Spray-drift	0.126
D4	Stream	0.459	Spray-drift	0.019
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.104	Spray-drift	0.233
R1	Stream	0.800	Run-off	0.924
R2	Stream	0.529	Spray-drift	0.450
R3	Stream	0.862	Run-off	0.444

* Not relevant for CEZ

Table 8.8-23: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, at BBCH 21 considering the half-life on crop canopy of 5.8 days

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.786	Spray-drift	0.372
D4	Pond	0.032	Spray-drift	0.063
D4	Stream	0.614	Spray-drift	0.018
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.058	Run-off	0.132
R1	Stream	0.545	Run-off	0.619
R2	Stream	0.719	Spray-drift	0.091
R3	Stream	0.767	Spray-drift	0.167

* Not relevant for CEZ

Table 8.8-24: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, till BBCH 89 considering the half-life on crop canopy of 5.8 days

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.572	Spray-drift	0.334
D4	Pond	0.058	Spray-drift	0.154
D4	Stream	0.482	Spray-drift	0.032
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.051	Spray-drift	0.119
R1	Stream	0.394	Spray-drift	0.058
R2	Stream	0.529	Spray-drift	0.503
R3	Stream	0.559	Run-off	0.875

* Not relevant for CEZ

Table 8.8-25: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, till BBCH 89 considering the half-life on crop canopy of 5.8 days

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.787	Spray-drift	0.787
D4	Pond	0.032	Spray-drift	0.032
D4	Stream	0.591	Spray-drift	0.591
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.032	Spray-drift	0.032
R1	Stream	0.545	Spray-drift	0.545
R2	Stream	0.731	Spray-drift	0.731
R3	Stream	0.768	Spray-drift	0.768

* Not relevant for CEZ

~~**FOCUS Step 3 for Zoxamide considering refined half-life on crop canopy**~~

~~**Table 8.8-22: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to vines at application rate of 3 x 180 g a.s./ha, at BBCH 14 considering refined half-life on crop canopy**~~

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominant entry route~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 3~~				
~~D6~~	~~Ditch~~	~~2.638~~	~~Drainage~~	~~2.754~~
~~R1~~	~~Pond~~	~~0.235~~	~~Run-off~~	~~0.623~~
~~R1~~	~~Stream~~	~~1.911~~	~~Spray-drift~~	~~0.377~~
~~R2~~	~~Stream~~	~~2.577~~	~~Run-off~~	~~0.219~~
~~R3~~	~~Stream~~	~~2.719~~	~~Run-off~~	~~0.656~~
~~R4~~	~~Stream~~	~~1.911~~	~~Spray-drift~~	~~1.317~~

~~**Table 8.8-23: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to vines at application rate of 1 x 180 g a.s./ha, at BBCH 14 considering refined half-life on crop canopy**~~

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominant entry route~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 3~~				
~~D6~~	~~Ditch~~	~~3.026~~	~~Spray-drift~~	~~0.822~~
~~R1~~	~~Pond~~	~~0.110~~	~~Spray-drift~~	~~0.254~~
~~R1~~	~~Stream~~	~~2.242~~	~~Spray-drift~~	~~0.255~~
~~R2~~	~~Stream~~	~~2.979~~	~~Spray-drift~~	~~0.178~~
~~R3~~	~~Stream~~	~~3.172~~	~~Spray-drift~~	~~0.612~~
~~R4~~	~~Stream~~	~~2.242~~	~~Spray-drift~~	~~0.253~~

~~**Table 8.8-24: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to vines at application rate of 3 x 180 g a.s./ha, till BBCH 79 considering refined half-life on crop canopy**~~

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominant entry route~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 3~~				
~~D6~~	~~Ditch~~	~~3.625~~	~~Drainage~~	~~4.655~~
~~R1~~	~~Pond~~	~~0.201~~	~~Run-off~~	~~0.458~~
~~R1~~	~~Stream~~	~~1.929~~	~~Run-off~~	~~0.280~~
~~R2~~	~~Stream~~	~~2.586~~	~~Run-off~~	~~0.218~~
~~R3~~	~~Stream~~	~~2.720~~	~~Run-off~~	~~0.664~~
~~R4~~	~~Stream~~	~~1.929~~	~~Run-off~~	~~0.294~~

~~**Table 8.8-25: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to vines at application rate of 1 x 180 g a.s./ha, till BBCH 79 considering refined half-life on crop canopy**~~

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominant entry route~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 3~~				
~~D6~~	~~Ditch~~	~~3.086~~	~~Spray-drift~~	~~3.360~~
~~R1~~	~~Pond~~	~~0.110~~	~~Spray-drift~~	~~0.213~~
~~R1~~	~~Stream~~	~~2.202~~	~~Spray-drift~~	~~0.173~~
~~R2~~	~~Stream~~	~~3.034~~	~~Spray-drift~~	~~0.231~~
~~R3~~	~~Stream~~	~~3.191~~	~~Spray-drift~~	~~0.715~~
~~R4~~	~~Stream~~	~~2.263~~	~~Spray-drift~~	~~0.318~~

~~**Table 8.8-26: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to pome fruit at application rate of 2 x 180 g a.s./ha, at BBCH 51 considering refined half-life on crop canopy**~~

	~~Waterbody~~	~~Max PEC_{sw} [µg/L]~~	~~Dominant entry route~~	~~Max PEC_{sed} [µg/kg]~~
~~Step 3~~				
~~D3~~	~~Ditch~~	~~12.05~~	~~Drainage~~	~~7.687~~
~~D4~~	~~Pond~~	~~1.210~~	~~Drainage~~	~~2.574~~
~~D4~~	~~Stream~~	~~12.68~~	~~Drainage~~	~~2.238~~
~~D5~~	~~Pond~~	~~1.335~~	~~Drainage~~	~~2.996~~
~~D5~~	~~Stream~~	~~13.69~~	~~Drainage~~	~~3.184~~
~~R1~~	~~Pond~~	~~1.335~~	~~Run-off~~	~~2.856~~
~~R1~~	~~Stream~~	~~9.700~~	~~Run-off~~	~~1.396~~
~~R2~~	~~Stream~~	~~13.00~~	~~Run-off~~	~~1.117~~
~~R3~~	~~Stream~~	~~13.69~~	~~Spray-drift~~	~~3.273~~
~~R4~~	~~Stream~~	~~9.697~~	~~Spray-drift~~	~~1.320~~

~~**Table 8.8-27: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to pome fruit at application rate of 1 x 180 g a.s./ha, at BBCH 51 considering refined half-life on crop canopy**~~

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominant entry route~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 3~~				
~~D3~~	~~Ditch~~	~~13.990~~	~~Spray-drift~~	~~7.888~~
~~D4~~	~~Pond~~	~~0.849~~	~~Spray-drift~~	~~1.800~~
~~D4~~	~~Stream~~	~~14.240~~	~~Spray-drift~~	~~1.095~~
~~D5~~	~~Pond~~	~~0.849~~	~~Spray-drift~~	~~1.862~~
~~D5~~	~~Stream~~	~~15.180~~	~~Spray-drift~~	~~1.067~~
~~R1~~	~~Pond~~	~~0.849~~	~~Spray-drift~~	~~1.686~~
~~R1~~	~~Stream~~	~~11.360~~	~~Spray-drift~~	~~1.551~~
~~R2~~	~~Stream~~	~~15.220~~	~~Spray-drift~~	~~1.129~~
~~R3~~	~~Stream~~	~~15.930~~	~~Spray-drift~~	~~2.917~~
~~R4~~	~~Stream~~	~~11.360~~	~~Spray-drift~~	~~1.546~~

~~**Table 8.8-28: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to pome fruit at application rate of 2 x 180 g a.s./ha, till BBCH 69 considering refined half-life on crop canopy**~~

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominant entry route~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 3~~				
~~D3~~	~~Ditch~~	~~12.050~~	~~Drainage~~	~~7.673~~
~~D4~~	~~Pond~~	~~1.403~~	~~Drainage~~	~~3.113~~
~~D4~~	~~Stream~~	~~12.290~~	~~Drainage~~	~~1.289~~
~~D5~~	~~Pond~~	~~1.329~~	~~Drainage~~	~~3.146~~
~~D5~~	~~Stream~~	~~12.950~~	~~Drainage~~	~~0.960~~
~~R1~~	~~Pond~~	~~1.335~~	~~Run-off~~	~~2.856~~
~~R1~~	~~Stream~~	~~9.700~~	~~Run-off~~	~~1.396~~
~~R2~~	~~Stream~~	~~13.020~~	~~Run-off~~	~~1.106~~
~~R3~~	~~Stream~~	~~13.640~~	~~Spray-drift~~	~~2.757~~
~~R4~~	~~Stream~~	~~9.697~~	~~Spray-drift~~	~~1.320~~

Table 8.8-29: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to pome fruit at application rate of 1 x 180 g a.s./ha, till BBCH 69 considering refined half-life on crop canopy

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	14.010	Spray-drift	8.765
D4	Pond	0.849	Spray-drift	1.802
D4	Stream	14.340	Spray-drift	1.232
D5	Pond	0.849	Spray-drift	1.862
D5	Stream	15.180	Spray-drift	1.067
R1	Pond	0.849	Spray-drift	1.686
R1	Stream	11.360	Spray-drift	1.551
R2	Stream	15.250	Spray-drift	1.156
R3	Stream	15.930	Spray-drift	2.917
R4	Stream	11.120	Spray-drift	0.954

Table 8.8-30: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, at BBCH 21 considering refined half-life on crop canopy

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
D3	Ditch	0.571	Spray-drift	0.306
D4	Pond	0.059	Spray-drift	0.126
D4	Stream	0.459	Spray-drift	0.019
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.088	Spray-drift	0.198
R1	Stream	0.540	Run-off	0.623
R2	Stream	0.529	Spray-drift	0.345
R3	Stream	0.695	Run-off	0.365

* Not relevant for CEZ

~~**Table 8.8-31: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, at BBCH 21 considering refined half-life on crop canopy**~~

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.786	Spray-drift	0.372
D4	Pond	0.032	Spray-drift	0.063
D4	Stream	0.614	Spray-drift	0.018
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.052	Run-off	0.119
R1	Stream	0.545	Spray-drift	0.510
R2	Stream	0.719	Spray-drift	0.081
R3	Stream	0.767	Spray-drift	0.167

* Not relevant for CEZ

~~**Table 8.8-32: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, till BBCH 89 considering refined half-life on crop canopy**~~

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 3				
D3	Ditch	0.572	Spray-drift	0.334
D4	Pond	0.058	Spray-drift	0.154
D4	Stream	0.482	Spray-drift	0.032
D6	Ditch	*	*	*
D6	Ditch	*	*	*
R1	Pond	0.051	Spray-drift	0.119
R1	Stream	0.394	Spray-drift	0.058
R2	Stream	0.529	Spray-drift	0.374
R3	Stream	0.558	Spray-drift	0.675

* Not relevant for CEZ

~~**Table 8.8-33: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, till BBCH 89 considering refined half-life on crop canopy**~~

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominant entry route~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 3~~				
~~D3~~	~~Ditch~~	~~0.787~~	~~Spray-drift~~	~~0.426~~
~~D4~~	~~Pond~~	~~0.032~~	~~Spray-drift~~	~~0.071~~
~~D4~~	~~Stream~~	~~0.591~~	~~Spray-drift~~	~~0.015~~
~~D6~~	~~Ditch~~	*	*	*
~~D6~~	~~Ditch~~	*	*	*
~~R1~~	~~Pond~~	~~0.032~~	~~Spray-drift~~	~~0.067~~
~~R1~~	~~Stream~~	~~0.545~~	~~Spray-drift~~	~~0.078~~
~~R2~~	~~Stream~~	~~0.731~~	~~Spray-drift~~	~~0.184~~
~~R3~~	~~Stream~~	~~0.768~~	~~Spray-drift~~	~~0.402~~

~~* Not relevant for CEZ~~

FOCUS Step 4 for Zoxamide considering endpoints based on LoEP

Table 8.8-26~~34~~: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to vines at application rate of 3 x 180 g a.s./ha, at BBCH 14 according to surface water Step 4 considering endpoints based on LoEP

PEC_{sw} (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	~~10~~ 20	10	~~20~~ 10
	No spray buffer (m)	~~10~~ 20	~~15~~ 10	~~20~~ 15	~~10~~ 20	15	~~20~~ 10
None	D6 Ditch	0.023	0.306	0.196	0.023	0.023	0.196
50 %		0.023	0.153	0.098	0.023	0.023	0.098
75 %		0.023	0.076	0.049	0.023	0.023	0.049
90 %		0.023	0.031	0.020	0.023	0.031	0.020
None	R1 Pond	0.004	0.100	0.075	0.004	0.004	0.074
50 %		0.004	0.053	0.041	0.004	0.004	0.037
75 %		0.004	0.031	0.026	0.004	0.004	0.019
90 %		0.004	0.019	0.017	0.004	0.012	0.008
None	R1 Stream	0.168	0.994	0.994	0.168	0.168	0.214
50 %		0.168	0.994	0.994	0.168	0.168	0.214
75 %		0.168	0.994	0.994	0.168	0.168	0.214
90 %		0.168	0.994	0.994	0.168	0.420	0.214
None	R2 Stream	0.028	0.361	0.231	0.028	0.028	0.231
50 %		0.028	0.180	0.116	0.028	0.028	0.116
75 %		0.028	0.090	0.066	0.028	0.028	0.058
90 %		0.028	0.066	0.066	0.028	0.036	0.023
None	R3 Stream	0.029	0.381	0.244	0.029	0.029	0.244
50 %		0.029	0.190	0.122	0.029	0.029	0.122
75 %		0.029	0.095	0.061	0.029	0.029	0.061
90 %		0.029	0.038	0.024	0.029	0.038	0.024
None	R4 Stream	0.070	1.774	1.774	0.070	0.070	0.413
50 %		0.070	1.774	1.774	0.070	0.070	0.413
75 %		0.070	1.774	1.774	0.070	0.070	0.413

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	~~10~~ 20	10	~~20~~ 10
	No spray buffer (m)	~~10~~ 20	~~15~~ 10	~~20~~ 15	~~10~~ 20	15	~~20~~ 10
90 %		0.070	1.774	1.774	0.070	0.788	0.413

Table 8.8-~~35~~27: Global maximum PEC$_{sw}$ values for Zoxamide following single application of GWN 10616 to vines at application rate of 1 x 180 g a.s./ha, at BBCH 14 according to surface water Step 4 considering endpoints based on LoEP

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D6 Ditch	0.663	0.360	0.232	0.663	0.360	0.232
50 %		0.332	0.180	0.116	0.332	0.180	0.116
75 %		0.166	0.090	0.058	0.166	0.090	0.058
90 %		0.066	0.036	0.023	0.066	0.036	0.023
None	R1 Pond	0.070	0.048	0.035	0.070	0.048	0.035
50 %		0.035	0.024	0.018	0.035	0.024	0.018
75 %		0.018	0.012	0.009	0.018	0.012	0.009
90 %		0.007	0.005	0.004	0.007	0.005	0.004
None	R1 Stream	0.592	0.322	0.208	0.592	0.322	0.208
50 %		0.296	0.168	0.168	0.296	0.161	0.104
75 %		0.168	0.168	0.168	0.148	0.080	0.052
90 %		0.168	0.168	0.168	0.071	0.071	0.036
None	R2 Stream	0.786	0.427	0.276	0.786	0.427	0.276
50 %		0.393	0.214	0.138	0.393	0.214	0.138
75 %		0.197	0.107	0.069	0.197	0.107	0.069
90 %		0.079	0.043	0.028	0.079	0.043	0.028
None	R3 Stream	0.837	0.455	0.294	0.837	0.455	0.294
50 %		0.419	0.227	0.147	0.419	0.227	0.147

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
75 %		0.209	0.114	0.073	0.209	0.114	0.073
90 %		0.084	0.045	0.029	0.084	0.045	0.029
None	R4 Stream	0.592	0.322	0.208	0.592	0.322	0.208
50 %		0.296	0.161	0.104	0.296	0.161	0.104
75 %		0.148	0.080	0.070	0.148	0.080	0.052
90 %		0.070	0.070	0.070	0.059	0.032	0.021

Table 8.8-~~36~~28: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to vines at application rate of 3 x 180 g a.s./ha, till BBCH 79 according to surface water Step 4 considering endpoints based on LoEP

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D6 Ditch	0.024	0.024	0.024	0.024	0.024	0.024
50 %		0.024	0.024	0.024	0.024	0.024	0.024
75 %		0.024	0.024	0.024	0.024	0.024	0.024
90 %		0.024	0.024	0.024	0.024	0.024	0.024
None	R1 Pond	0.004	0.004	0.004	0.004	0.004	0.004
50 %		0.004	0.004	0.004	0.004	0.004	0.004
75 %		0.004	0.004	0.004	0.004	0.004	0.004
90 %		0.004	0.004	0.004	0.004	0.004	0.004
None	R1 Stream	0.020	0.020	0.020	0.020	0.020	0.020
50 %		0.020	0.020	0.020	0.020	0.020	0.020
75 %		0.020	0.020	0.020	0.020	0.020	0.020
90 %		0.020	0.020	0.020	0.020	0.020	0.020
None	R2 Stream	0.028	0.028	0.028	0.028	0.028	0.028

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
50 %		0.028	0.028	0.028	0.028	0.028	0.028
75 %		0.028	0.028	0.028	0.028	0.028	0.028
90 %		0.028	0.028	0.028	0.028	0.028	0.028
None	R3 Stream	0.493	0.493	0.493	0.493	0.493	0.493
50 %		0.493	0.493	0.493	0.493	0.493	0.493
75 %		0.493	0.493	0.493	0.493	0.493	0.493
90 %		0.493	0.493	0.493	0.493	0.493	0.493
None	R4 Stream	0.086	0.086	0.086	0.086	0.086	0.086
50 %		0.086	0.086	0.086	0.086	0.086	0.086
75 %		0.086	0.086	0.086	0.086	0.086	0.086
90 %		0.086	0.086	0.086	0.086	0.086	0.086

Table 8.8-~~37~~29: Global maximum PEC$_{sw}$ values for Zoxamide following single application of GWN 10616 to vines at application rate of 1 x 180 g a.s./ha, till BBCH 79 according to surface water Step 4 considering endpoints based on LoEP

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D6 Ditch	0.676	0.367	0.237	0.676	0.367	0.237
50 %		0.338	0.184	0.119	0.338	0.184	0.119
75 %		0.169	0.092	0.059	0.169	0.092	0.059
90 %		0.068	0.037	0.024	0.068	0.037	0.024
None	R1 Pond	0.070	0.048	0.035	0.070	0.048	0.035
50 %		0.035	0.024	0.018	0.035	0.024	0.018
75 %		0.018	0.012	0.009	0.018	0.012	0.009
90 %		0.007	0.005	0.004	0.007	0.005	0.004

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	R1 Stream	0.581	0.316	0.204	0.581	0.316	0.204
50 %		0.291	0.158	0.102	0.291	0.158	0.102
75 %		0.145	0.079	0.051	0.145	0.079	0.051
90 %		0.058	0.032	0.020	0.058	0.032	0.020
None	R2 Stream	0.801	0.435	0.281	0.801	0.435	0.281
50 %		0.401	0.218	0.140	0.401	0.218	0.140
75 %		0.200	0.109	0.070	0.200	0.109	0.070
90 %		0.080	0.044	0.028	0.080	0.044	0.028
None	R3 Stream	0.842	0.493	0.493	0.842	0.458	0.295
50 %		0.493	0.493	0.493	0.421	0.229	0.148
75 %		0.493	0.493	0.493	0.221	0.221	0.115
90 %		0.493	0.493	0.493	0.221	0.221	0.115
None	R4 Stream	0.597	0.325	0.210	0.597	0.325	0.210
50 %		0.299	0.162	0.105	0.299	0.162	0.105
75 %		0.149	0.086	0.086	0.149	0.081	0.052
90 %		0.086	0.086	0.086	0.060	0.038	0.021

Table 8.8-~~38~~30: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to pome fruit at application rate of 2 x 180 g a.s./ha, at BBCH 51 according to surface water Step 4 considering endpoints based on LoEP

PEC_{sw} (µg/L)	Scenario	STEP 4							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D3 Ditch	0.017	0.017	0.017	0.017	0.017	0.017	0.017	0.017
50 %		0.017	0.017	0.017	0.017	0.017	0.017	0.017	0.017
75 %		0.017	0.017	0.017	0.017	0.017	0.017	0.017	0.017
90 %		0.017	0.017	0.017	0.017	0.017	0.017	0.017	0.017
None	D4 Pond	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
50 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
75 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
90 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
None	D4 Stream	0.019	0.019	0.019	0.019	0.019	0.019	0.019	0.019
50 %		0.019	0.019	0.019	0.019	0.019	0.019	0.019	0.019
75 %		0.019	0.019	0.019	0.019	0.019	0.019	0.019	0.019
90 %		0.019	0.019	0.019	0.019	0.019	0.019	0.019	0.019
None	D5 Pond	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
50 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
75 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
90 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
None	D5 Stream	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
50 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
75 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
90 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
None	R1 Pond	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
50 %		0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
75 %		0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
90 %		0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
None	R1 Stream	0.457	0.457	0.457	0.457	0.457	0.457	0.457	0.457

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
50 %		0.457	0.457	0.457	0.457	0.457	0.457	0.457	0.457
75 %		0.457	0.457	0.457	0.457	0.457	0.457	0.457	0.457
90 %		0.457	0.457	0.457	0.457	0.457	0.457	0.457	0.457
None	R2 Stream	0.158	0.158	0.158	0.158	0.158	0.158	0.158	0.158
50 %		0.158	0.158	0.158	0.158	0.158	0.158	0.158	0.158
75 %		0.158	0.158	0.158	0.158	0.158	0.158	0.158	0.158
90 %		0.158	0.158	0.158	0.158	0.158	0.158	0.158	0.158
None	R3 Stream	0.022	0.022	0.022	0.022	0.022	0.022	0.022	0.022
50 %		0.022	0.022	0.022	0.022	0.022	0.022	0.022	0.022
75 %		0.022	0.022	0.022	0.022	0.022	0.022	0.022	0.022
90 %		0.022	0.022	0.022	0.022	0.022	0.022	0.022	0.022
None	R4 Stream	0.537	0.537	0.537	0.537	0.537	0.537	0.537	0.537
50 %		0.537	0.537	0.537	0.537	0.537	0.537	0.537	0.537
75 %		0.537	0.537	0.537	0.537	0.537	0.537	0.537	0.537
90 %		0.537	0.537	0.537	0.537	0.537	0.537	0.537	0.537

Table 8.8-3931: Global maximum PEC_{sw} values for Zoxamide following single application of GWN 10616 to pome fruit at application rate of 1 x 180 g a.s./ha, at BBCH 51 according to surface water Step 4 considering endpoints based on LoEP

PEC_{sw} (µg/L)	Scenario	STEP 4							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D3 Ditch	6.762	3.041	1.546	0.175	6.762	3.041	1.546	0.175
50 %		3.381	1.521	0.773	0.087	3.381	1.521	0.773	0.087
75 %		1.690	0.760	0.387	0.044	1.690	0.760	0.387	0.044
90 %		0.676	0.304	0.155	0.017	0.676	0.304	0.155	0.017
None	D4 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.008	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.003	0.052	0.028	0.017	0.003
None	D4 Stream	7.514	3.381	1.718	0.194	7.514	3.381	1.718	0.194
50 %		3.757	1.690	0.859	0.097	3.757	1.690	0.859	0.097
75 %		1.878	0.845	0.429	0.049	1.878	0.845	0.429	0.049
90 %		0.751	0.338	0.172	0.019	0.751	0.338	0.172	0.019
None	D5 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.008	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.003	0.052	0.028	0.017	0.003
None	D5 Stream	8.009	3.604	1.831	0.207	8.009	3.604	1.831	0.207
50 %		4.004	1.801	0.915	0.103	4.004	1.801	0.915	0.103
75 %		2.002	0.900	0.458	0.052	2.002	0.900	0.458	0.052
90 %		0.801	0.360	0.183	0.021	0.801	0.360	0.183	0.021
None	R1 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.017	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.010	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.018	0.006	0.052	0.028	0.017	0.003
None	R1 Stream	5.995	2.698	1.371	0.457	5.995	2.698	1.371	0.155

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
50 %		2.998	1.348	0.685	0.457	2.998	1.348	0.685	0.101
75 %		1.499	0.674	0.457	0.457	1.499	0.674	0.343	0.101
90 %		0.600	0.457	0.457	0.457	0.600	0.270	0.137	0.101
None	R2 Stream	8.032	3.614	1.836	0.207	8.032	3.614	1.836	0.207
50 %		4.016	1.807	0.918	0.158	4.016	1.807	0.918	0.104
75 %		2.008	0.903	0.459	0.158	2.008	0.903	0.459	0.052
90 %		0.803	0.361	0.184	0.158	0.803	0.361	0.184	0.037
None	R3 Stream	8.404	3.782	1.921	0.217	8.404	3.782	1.921	0.217
50 %		4.202	1.890	0.961	0.109	4.202	1.890	0.961	0.109
75 %		2.101	0.945	0.480	0.054	2.101	0.945	0.480	0.054
90 %		0.840	0.378	0.192	0.022	0.840	0.378	0.192	0.022
None	R4 Stream	5.994	2.697	1.370	0.537	5.994	2.697	1.370	0.155
50 %		2.997	1.348	0.685	0.537	2.997	1.348	0.685	0.116
75 %		1.498	0.674	0.537	0.537	1.498	0.674	0.343	0.116
90 %		0.599	0.537	0.537	0.537	0.599	0.270	0.137	0.116

Table 8.8-~~40~~32: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to pome fruit at application rate of 2 x 180 g a.s./ha, till BBCH 69 according to surface water Step 4 considering endpoints based on LoEP

PEC_{sw} (µg/L)	Scenario	STEP 4							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D3 Ditch	0.017	0.017	0.017	0.017	0.017	0.017	0.017	0.017
50 %		0.017	0.017	0.017	0.017	0.017	0.017	0.017	0.017
75 %		0.017	0.017	0.017	0.017	0.017	0.017	0.017	0.017
90 %		0.017	0.017	0.017	0.017	0.017	0.017	0.017	0.017
None	D4 Pond	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
50 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
75 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
90 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
None	D4 Stream	0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020
50 %		0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020
75 %		0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020
90 %		0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020
None	D5 Pond	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
50 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
75 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
90 %		0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
None	D5 Stream	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
50 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
75 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
90 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
None	R1 Pond	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
50 %		0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
75 %		0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
90 %		0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
None	R1 Stream	0.457	0.457	0.457	0.457	0.457	0.457	0.457	0.457

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4**							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
50 %		0.457	0.457	0.457	0.457	0.457	0.457	0.457	0.457
75 %		0.457	0.457	0.457	0.457	0.457	0.457	0.457	0.457
90 %		0.457	0.457	0.457	0.457	0.457	0.457	0.457	0.457
None	R2 Stream	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
50 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
75 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
90 %		0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
None	R3 Stream	0.022	0.022	0.022	0.022	0.022	0.022	0.022	0.022
50 %		0.022	0.022	0.022	0.022	0.022	0.022	0.022	0.022
75 %		0.022	0.022	0.022	0.022	0.022	0.022	0.022	0.022
90 %		0.022	0.022	0.022	0.022	0.022	0.022	0.022	0.022
None	R4 Stream	0.792	0.792	0.792	0.792	0.792	0.792	0.792	0.792
50 %		0.792	0.792	0.792	0.792	0.792	0.792	0.792	0.792
75 %		0.792	0.792	0.792	0.792	0.792	0.792	0.792	0.792
90 %		0.792	0.792	0.792	0.792	0.792	0.792	0.792	0.792

Table 8.8-~~41~~33: Global maximum PEC$_{sw}$ values for Zoxamide following single application of GWN 10616 to pome fruit at application rate of 1 x 180 g a.s./ha, till BBCH 69 according to surface water Step 4 considering endpoints based on LoEP

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4**							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D3 Ditch	6.762	3.041	1.546	0.175	6.762	3.041	1.546	0.175
50 %		3.381	1.521	0.773	0.087	3.381	1.521	0.773	0.087
75 %		1.690	0.760	0.387	0.044	1.690	0.760	0.387	0.044
90 %		0.676	0.304	0.155	0.017	0.676	0.304	0.155	0.017

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D4 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.008	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.003	0.052	0.028	0.017	0.003
None	D4 Stream	7.569	3.406	1.730	0.195	7.569	3.406	1.730	0.195
50 %		3.784	1.702	0.865	0.098	3.784	1.702	0.865	0.098
75 %		1.892	0.851	0.433	0.049	1.892	0.851	0.433	0.049
90 %		0.757	0.341	0.173	0.020	0.757	0.341	0.173	0.020
None	D5 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.008	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.003	0.052	0.028	0.017	0.003
None	D5 Stream	8.009	3.604	1.831	0.207	8.009	3.604	1.831	0.207
50 %		4.004	1.801	0.915	0.103	4.004	1.801	0.915	0.103
75 %		2.002	0.900	0.458	0.052	2.002	0.900	0.458	0.052
90 %		0.801	0.360	0.183	0.021	0.801	0.360	0.183	0.021
None	R1 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.017	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.010	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.018	0.006	0.052	0.028	0.017	0.003
None	R1 Stream	5.995	2.698	1.371	0.457	5.995	2.698	1.371	0.155
50 %		2.998	1.348	0.685	0.457	2.998	1.348	0.685	0.101
75 %		1.499	0.674	0.457	0.457	1.499	0.674	0.343	0.101
90 %		0.600	0.457	0.457	0.457	0.600	0.270	0.137	0.101
None	R2 Stream	8.049	3.622	1.840	0.208	8.049	3.622	1.840	0.208
50 %		4.025	1.810	0.920	0.104	4.025	1.810	0.920	0.104
75 %		2.012	0.905	0.460	0.052	2.012	0.905	0.460	0.052
90 %		0.805	0.362	0.184	0.021	0.805	0.362	0.184	0.021

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	R3 Stream	8.404	3.782	1.921	0.217	8.404	3.782	1.921	0.217
50 %		4.202	1.890	0.961	0.109	4.202	1.890	0.961	0.109
75 %		2.101	0.945	0.480	0.054	2.101	0.945	0.480	0.054
90 %		0.840	0.378	0.192	0.022	0.840	0.378	0.192	0.022
None	R4 Stream	5.870	2.641	1.342	0.792	5.870	2.641	1.342	0.171
50 %		2.935	1.320	0.792	0.792	2.935	1.320	0.671	0.171
75 %		1.467	0.792	0.792	0.792	1.467	0.660	0.335	0.171
90 %		0.792	0.792	0.792	0.792	0.587	0.335	0.171	0.171

Table 8.8-~~42~~34: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, at BBCH 21 according to surface water Step 4 considering endpoints based on LoEP

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.007	0.007	0.007	0.007	0.007	0.007
50 %		0.007	0.007	0.007	0.007	0.007	0.007
75 %		0.007	0.007	0.007	0.007	0.007	0.007
90 %		0.007	0.007	0.007	0.007	0.007	0.007
None	D4 Pond	0.001	0.001	0.001	0.001	0.001	0.001
50 %		0.001	0.001	0.001	0.001	0.001	0.001
75 %		0.001	0.001	0.001	0.001	0.001	0.001
90 %		0.001	0.001	0.001	0.001	0.001	0.001
None	D4 Stream	0.007	0.007	0.007	0.007	0.007	0.007
50 %		0.007	0.007	0.007	0.007	0.007	0.007
75 %		0.007	0.007	0.007	0.007	0.007	0.007

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
90 %		0.007	0.007	0.007	0.007	0.007	0.007
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.041	0.041	0.041	0.041	0.041	0.041
50 %		0.041	0.041	0.041	0.041	0.041	0.041
75 %		0.041	0.041	0.041	0.041	0.041	0.041
90 %		0.041	0.041	0.041	0.041	0.041	0.041
None	R1 Stream	0.605	0.605	0.605	0.605	0.605	0.605
50 %		0.605	0.605	0.605	0.605	0.605	0.605
75 %		0.605	0.605	0.605	0.605	0.605	0.605
90 %		0.605	0.605	0.605	0.605	0.605	0.605
None	R2 Stream	0.166	0.166	0.166	0.166	0.166	0.166
50 %		0.166	0.166	0.166	0.166	0.166	0.166
75 %		0.166	0.166	0.166	0.166	0.166	0.166
90 %		0.166	0.166	0.166	0.166	0.166	0.166
None	R3 Stream	0.148	0.148	0.148	0.148	0.148	0.148
50 %		0.148	0.148	0.148	0.148	0.148	0.148
75 %		0.148	0.148	0.148	0.148	0.148	0.148
90 %		0.148	0.148	0.148	0.148	0.148	0.148

* D6 not relevant for CEZ

Table 8.8-~~43~~35: Global maximum PEC_{sw} values for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, at BBCH 21 according to surface water Step 4 considering endpoints based on LoEP

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.137	0.093	0.071	0.137	0.093	0.071
50 %		0.068	0.047	0.035	0.068	0.047	0.035
75 %		0.034	0.023	0.018	0.034	0.023	0.018
90 %		0.014	0.009	0.007	0.014	0.009	0.007
None	D4 Pond	0.020	0.016	0.014	0.020	0.016	0.014
50 %		0.010	0.008	0.007	0.010	0.008	0.007
75 %		0.005	0.004	0.003	0.005	0.004	0.003
90 %		0.002	0.002	0.001	0.002	0.002	0.001
None	D4 Stream	0.137	0.094	0.071	0.137	0.094	0.071
50 %		0.069	0.047	0.036	0.069	0.047	0.036
75 %		0.034	0.023	0.018	0.034	0.023	0.018
90 %		0.014	0.009	0.007	0.014	0.009	0.007
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.056	0.053	0.051	0.033	0.029	0.019
50 %		0.048	0.046	0.045	0.024	0.023	0.014
75 %		0.044	0.043	0.042	0.020	0.019	0.011
90 %		0.041	0.041	0.041	0.018	0.017	0.009
None	R1 Stream	0.605	0.605	0.605	0.275	0.275	0.144
50 %		0.605	0.605	0.605	0.275	0.275	0.144
75 %		0.605	0.605	0.605	0.275	0.275	0.144
90 %		0.605	0.605	0.605	0.275	0.275	0.144
None	R2 Stream	0.166	0.166	0.166	0.161	0.110	0.083
50 %		0.166	0.166	0.166	0.080	0.074	0.042

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
75 %		0.166	0.166	0.166	0.074	0.074	0.038
90 %		0.166	0.166	0.166	0.074	0.074	0.038
None	R3 Stream	0.171	0.148	0.148	0.171	0.117	0.089
50 %		0.148	0.148	0.148	0.086	0.067	0.045
75 %		0.148	0.148	0.148	0.067	0.067	0.035
90 %		0.148	0.148	0.148	0.067	0.067	0.035

* D6 not relevant for CEZ

Table 8.8-4436: **Global maximum PEC$_{sw}$ values for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, till BBCH 89 according to surface water Step 4 considering endpoints based on LoEP**

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.096	0.065	0.049	0.096	0.065	0.049
50 %		0.048	0.033	0.025	0.048	0.033	0.025
75 %		0.024	0.016	0.012	0.024	0.016	0.012
90 %		0.010	0.007	0.005	0.010	0.007	0.005
None	D4 Pond	0.037	0.029	0.024	0.037	0.029	0.024
50 %		0.018	0.015	0.012	0.018	0.015	0.012
75 %		0.009	0.007	0.006	0.009	0.007	0.006
90 %		0.005	0.004	0.004	0.005	0.004	0.004
None	D4 Stream	0.105	0.071	0.054	0.105	0.071	0.054
50 %		0.052	0.035	0.027	0.052	0.035	0.027
75 %		0.026	0.018	0.018	0.026	0.018	0.018
90 %		0.018	0.018	0.018	0.018	0.018	0.018
None	D6 Ditch	*	*	*	*	*	*

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
	1st crop						
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.032	0.026	0.021	0.032	0.026	0.021
50 %		0.016	0.013	0.011	0.016	0.013	0.011
75 %		0.008	0.007	0.007	0.008	0.006	0.005
90 %		0.007	0.007	0.007	0.003	0.003	0.002
None	R1 Stream	0.099	0.099	0.099	0.086	0.058	0.044
50 %		0.099	0.099	0.099	0.044	0.044	0.023
75 %		0.099	0.099	0.099	0.044	0.044	0.023
90 %		0.099	0.099	0.099	0.044	0.044	0.023
None	R2 Stream	0.343	0.343	0.343	0.153	0.153	0.079
50 %		0.343	0.343	0.343	0.153	0.153	0.079
75 %		0.343	0.343	0.343	0.153	0.153	0.079
90 %		0.343	0.343	0.343	0.153	0.153	0.079
None	R3 Stream	0.716	0.716	0.716	0.327	0.327	0.171
50 %		0.716	0.716	0.716	0.327	0.327	0.171
75 %		0.716	0.716	0.716	0.327	0.327	0.171
90 %		0.716	0.716	0.716	0.327	0.327	0.171

* D6 not relevant for CEZ

Table 8.8-4537: Global maximum PEC$_{sw}$ values for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, till BBCH 89 according to surface water Step 4 considering endpoints based on LoEP

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.137	0.093	0.071	0.137	0.093	0.071
50 %		0.068	0.047	0.036	0.068	0.047	0.036
75 %		0.034	0.023	0.018	0.034	0.023	0.018
90 %		0.014	0.009	0.007	0.014	0.009	0.007
None	D4 Pond	0.020	0.016	0.014	0.020	0.016	0.014
50 %		0.010	0.008	0.007	0.010	0.008	0.007
75 %		0.005	0.004	0.003	0.005	0.004	0.003
90 %		0.002	0.002	0.001	0.002	0.002	0.001
None	D4 Stream	0.132	0.090	0.069	0.132	0.090	0.069
50 %		0.066	0.045	0.034	0.066	0.045	0.034
75 %		0.033	0.023	0.017	0.033	0.023	0.017
90 %		0.013	0.009	0.007	0.013	0.009	0.007
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.020	0.016	0.014	0.020	0.016	0.014
50 %		0.010	0.008	0.007	0.010	0.008	0.007
75 %		0.006	0.006	0.006	0.005	0.004	0.003
90 %		0.005	0.005	0.005	0.002	0.002	0.001
None	R1 Stream	0.122	0.083	0.080	0.122	0.083	0.063
50 %		0.080	0.080	0.080	0.061	0.042	0.032
75 %		0.080	0.080	0.080	0.036	0.036	0.019
90 %		0.080	0.080	0.080	0.036	0.036	0.019
None	R2 Stream	0.256	0.256	0.256	0.163	0.114	0.085
50 %		0.256	0.256	0.256	0.114	0.114	0.059

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
75 %		0.256	0.256	0.256	0.114	0.114	0.059
90 %		0.256	0.256	0.256	0.114	0.114	0.059
None	R3 Stream	0.483	0.483	0.483	0.220	0.220	0.115
50 %		0.483	0.483	0.483	0.220	0.220	0.115
75 %		0.483	0.483	0.483	0.220	0.220	0.115
90 %		0.483	0.483	0.483	0.220	0.220	0.115

* D6 not relevant for CEZ

FOCUS Step 4 for Zoxamide considering the half-life on crop canopy of 5.8 days

Table 8.8-38: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, at BBCH 21 according to surface water Step 4 considering the half-life on crop canopy of 5.8 days

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.096	0.065	0.049	0.096	0.065	0.049
50 %		0.048	0.033	0.025	0.048	0.033	0.025
75 %		0.024	0.016	0.012	0.024	0.016	0.012
90 %		0.010	0.007	0.005	0.010	0.007	0.005
None	D4 Pond	0.037	0.030	0.025	0.037	0.030	0.025
50 %		0.019	0.015	0.012	0.019	0.015	0.012
75 %		0.009	0.007	0.006	0.009	0.007	0.006
90 %		0.004	0.003	0.002	0.004	0.003	0.002
None	D4 Stream	0.100	0.068	0.051	0.100	0.068	0.051
50 %		0.050	0.034	0.026	0.050	0.034	0.026
75 %		0.025	0.017	0.013	0.025	0.017	0.013

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
90 %		0.010	0.007	0.005	0.010	0.007	0.005
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.074	0.067	0.063	0.051	0.044	0.031
50 %		0.057	0.054	0.051	0.033	0.030	0.020
75 %		0.048	0.047	0.046	0.025	0.023	0.014
90 %		0.045	0.044	0.044	0.019	0.019	0.010
None	R1 Stream	0.648	0.648	0.648	0.295	0.295	0.154
50 %		0.648	0.648	0.648	0.295	0.295	0.154
75 %		0.648	0.648	0.648	0.295	0.295	0.154
90 %		0.648	0.648	0.648	0.295	0.295	0.154
None	R2 Stream	0.407	0.407	0.407	0.182	0.182	0.094
50 %		0.407	0.407	0.407	0.182	0.182	0.094
75 %		0.407	0.407	0.407	0.182	0.182	0.094
90 %		0.407	0.407	0.407	0.182	0.182	0.094
None	R3 Stream	0.774	0.774	0.774	0.351	0.351	0.184
50 %		0.774	0.774	0.774	0.351	0.351	0.184
75 %		0.774	0.774	0.774	0.351	0.351	0.184
90 %		0.774	0.774	0.774	0.351	0.351	0.184

* D6 not relevant for CEZ

Table 8.8-39: Global maximum PEC_{sw} values for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, at BBCH 21 according to surface water Step 4 considering the half-life on crop canopy of 5.8 days

PEC_{sw} (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.137	0.093	0.071	0.137	0.093	0.071
50 %		0.068	0.047	0.035	0.068	0.047	0.035
75 %		0.034	0.023	0.018	0.034	0.023	0.018
90 %		0.014	0.009	0.007	0.014	0.009	0.007
None	D4 Pond	0.020	0.016	0.014	0.020	0.016	0.014
50 %		0.010	0.008	0.007	0.010	0.008	0.007
75 %		0.005	0.004	0.003	0.005	0.004	0.003
90 %		0.002	0.002	0.001	0.002	0.002	0.001
None	D4 Stream	0.137	0.094	0.071	0.137	0.094	0.071
50 %		0.069	0.047	0.036	0.069	0.047	0.036
75 %		0.034	0.023	0.018	0.034	0.023	0.018
90 %		0.014	0.009	0.007	0.014	0.009	0.007
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.049	0.045	0.043	0.030	0.026	0.018
50 %		0.040	0.039	0.038	0.021	0.020	0.012
75 %		0.036	0.035	0.035	0.017	0.016	0.009
90 %		0.034	0.033	0.033	0.015	0.014	0.008
None	R1 Stream	0.490	0.490	0.490	0.223	0.223	0.117
50 %		0.490	0.490	0.490	0.223	0.223	0.117
75 %		0.490	0.490	0.490	0.223	0.223	0.117
90 %		0.490	0.490	0.490	0.223	0.223	0.117
None	R2 Stream	0.161	0.138	0.138	0.161	0.110	0.083
50 %		0.138	0.138	0.138	0.080	0.061	0.042

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
75 %		0.138	0.138	0.138	0.061	0.061	0.032
90 %		0.138	0.138	0.138	0.061	0.061	0.032
None	R3 Stream	0.171	0.129	0.129	0.171	0.117	0.089
50 %		0.129	0.129	0.129	0.086	0.058	0.045
75 %		0.129	0.129	0.129	0.058	0.058	0.031
90 %		0.129	0.129	0.129	0.058	0.058	0.031

* D6 not relevant for CEZ

Table 8.8-40: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, till BBCH 89 according to surface water Step 4 considering the half-life on crop canopy of 5.8 days

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.096	0.065	0.049	0.096	0.065	0.049
50 %		0.048	0.033	0.025	0.048	0.033	0.025
75 %		0.024	0.016	0.012	0.024	0.016	0.012
90 %		0.010	0.007	0.005	0.010	0.007	0.005
None	D4 Pond	0.037	0.029	0.024	0.037	0.029	0.024
50 %		0.018	0.015	0.012	0.018	0.015	0.012
75 %		0.009	0.007	0.006	0.009	0.007	0.006
90 %		0.004	0.004	0.003	0.004	0.004	0.003
None	D4 Stream	0.105	0.071	0.054	0.105	0.071	0.054
50 %		0.052	0.035	0.027	0.052	0.035	0.027
75 %		0.026	0.018	0.014	0.026	0.018	0.014
90 %		0.014	0.014	0.014	0.014	0.014	0.014

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.032	0.026	0.021	0.032	0.026	0.021
50 %		0.016	0.013	0.011	0.016	0.013	0.011
75 %		0.008	0.006	0.005	0.008	0.006	0.005
90 %		0.004	0.004	0.004	0.003	0.003	0.002
None	R1 Stream	0.086	0.059	0.059	0.086	0.058	0.044
50 %		0.059	0.059	0.059	0.043	0.029	0.022
75 %		0.059	0.059	0.059	0.027	0.027	0.014
90 %		0.059	0.059	0.059	0.027	0.027	0.014
None	R2 Stream	0.291	0.291	0.291	0.130	0.130	0.067
50 %		0.291	0.291	0.291	0.130	0.130	0.067
75 %		0.291	0.291	0.291	0.130	0.130	0.067
90 %		0.291	0.291	0.291	0.130	0.130	0.067
None	R3 Stream	0.556	0.556	0.556	0.254	0.254	0.133
50 %		0.556	0.556	0.556	0.254	0.254	0.133
75 %		0.556	0.556	0.556	0.254	0.254	0.133
90 %		0.556	0.556	0.556	0.254	0.254	0.133

* D6 not relevant for CEZ

Table 8.8-41: Global maximum PEC_{sw} values for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, till BBCH 89 according to surface water Step 4 considering the half-life on crop canopy of 5.8 days

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.137	0.093	0.071	0.137	0.093	0.071
50 %		0.068	0.047	0.036	0.068	0.047	0.036
75 %		0.034	0.023	0.018	0.034	0.023	0.018
90 %		0.014	0.009	0.007	0.014	0.009	0.007
None	D4 Pond	0.020	0.016	0.014	0.020	0.016	0.014
50 %		0.010	0.008	0.007	0.010	0.008	0.007
75 %		0.005	0.004	0.003	0.005	0.004	0.003
90 %		0.002	0.002	0.001	0.002	0.002	0.001
None	D4 Stream	0.132	0.090	0.069	0.132	0.090	0.069
50 %		0.066	0.045	0.034	0.066	0.045	0.034
75 %		0.033	0.023	0.017	0.033	0.023	0.017
90 %		0.013	0.009	0.007	0.013	0.009	0.007
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.020	0.016	0.014	0.020	0.016	0.014
50 %		0.010	0.008	0.007	0.010	0.008	0.007
75 %		0.005	0.004	0.004	0.005	0.004	0.003
90 %		0.003	0.003	0.003	0.002	0.002	0.001
None	R1 Stream	0.122	0.083	0.063	0.122	0.083	0.063
50 %		0.061	0.048	0.048	0.061	0.042	0.032
75 %		0.048	0.048	0.048	0.030	0.021	0.016
90 %		0.048	0.048	0.048	0.021	0.021	0.011
None	R2 Stream	0.231	0.231	0.231	0.163	0.112	0.085
50 %		0.231	0.231	0.231	0.103	0.103	0.053

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
75 %		0.231	0.231	0.231	0.103	0.103	0.053
90 %		0.231	0.231	0.231	0.103	0.103	0.053
None	R3 Stream	0.371	0.371	0.371	0.172	0.169	0.089
50 %		0.371	0.371	0.371	0.169	0.169	0.089
75 %		0.371	0.371	0.371	0.169	0.169	0.089
90 %		0.371	0.371	0.371	0.169	0.169	0.089

* D6 not relevant for CEZ

~~FOCUS Step 4 for Zoxamide considering refined half-life on crop canopy~~

~~Table 8.8-46: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to vines at application rate of 3 x 180 g a.s./ha, at BBCH 14 according to surface water Step 4 considering refined half-life on crop canopy~~

~~**PEC_{sw} (µg/L)**~~	~~**Scenario**~~	~~**STEP 4**~~					
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~None~~	~~None~~	~~None~~	~~10~~	~~10~~	~~20~~
	~~No spray buffer (m)~~	~~10~~	~~15~~	~~20~~	~~10~~	~~15~~	~~20~~
~~None~~	~~D6 Ditch~~	~~0.567~~	~~0.306~~	~~0.196~~	~~0.567~~	~~0.306~~	~~0.196~~
~~50 %~~		~~0.283~~	~~0.153~~	~~0.098~~	~~0.283~~	~~0.153~~	~~0.098~~
~~75 %~~		~~0.142~~	~~0.076~~	~~0.049~~	~~0.142~~	~~0.076~~	~~0.049~~
~~90 %~~		~~0.057~~	~~0.031~~	~~0.020~~	~~0.057~~	~~0.031~~	~~0.020~~
~~None~~	~~R1 Pond~~	~~0.149~~	~~0.100~~	~~0.074~~	~~0.149~~	~~0.100~~	~~0.074~~
~~50 %~~		~~0.075~~	~~0.052~~	~~0.040~~	~~0.075~~	~~0.050~~	~~0.037~~
~~75 %~~		~~0.040~~	~~0.030~~	~~0.024~~	~~0.037~~	~~0.025~~	~~0.019~~
~~90 %~~		~~0.022~~	~~0.018~~	~~0.016~~	~~0.016~~	~~0.012~~	~~0.008~~
~~None~~	~~R1 Stream~~	~~0.899~~	~~0.899~~	~~0.899~~	~~0.496~~	~~0.380~~	~~0.194~~
~~50 %~~		~~0.899~~	~~0.899~~	~~0.899~~	~~0.380~~	~~0.380~~	~~0.194~~
~~75 %~~		~~0.899~~	~~0.899~~	~~0.899~~	~~0.380~~	~~0.380~~	~~0.194~~

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
90 %		0.899	0.899	0.899	0.380	0.380	0.194
None	R2 Stream	0.669	0.361	0.231	0.669	0.361	0.231
50 %		0.334	0.180	0.116	0.334	0.180	0.116
75 %		0.167	0.090	0.058	0.167	0.090	0.058
90 %		0.067	0.054	0.054	0.067	0.036	0.023
None	R3 Stream	0.706	0.381	0.244	0.706	0.381	0.244
50 %		0.353	0.190	0.122	0.353	0.190	0.122
75 %		0.176	0.095	0.061	0.176	0.095	0.061
90 %		0.071	0.038	0.024	0.071	0.038	0.024
None	R4 Stream	1.485	1.485	1.485	0.648	0.648	0.338
50 %		1.485	1.485	1.485	0.648	0.648	0.338
75 %		1.485	1.485	1.485	0.648	0.648	0.338
90 %		1.485	1.485	1.485	0.648	0.648	0.338

Table 8.8-47: Global maximum PEC$_{sw}$ values for Zoxamide following single application of GWN 10616 to vines at application rate of 1 x 180 g a.s./ha, at BBCH 14 according to surface water Step 4 considering refined half-life on crop canopy

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D6 Ditch	0.663	0.360	0.232	0.663	0.360	0.232
50 %		0.332	0.180	0.116	0.332	0.180	0.116
75 %		0.166	0.090	0.058	0.166	0.090	0.058
90 %		0.066	0.036	0.023	0.066	0.036	0.023
None	R1 Pond	0.070	0.048	0.035	0.070	0.048	0.035
50 %		0.035	0.024	0.018	0.035	0.024	0.018

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
75 %		0.018	0.012	0.009	0.018	0.012	0.009
90 %		0.007	0.005	0.004	0.007	0.005	0.004
None	R1 Stream	0.592	0.322	0.208	0.592	0.322	0.208
50 %		0.296	0.161	0.154	0.296	0.161	0.104
75 %		0.154	0.154	0.154	0.148	0.080	0.052
90 %		0.154	0.154	0.154	0.065	0.065	0.033
None	R2 Stream	0.786	0.427	0.276	0.786	0.427	0.276
50 %		0.393	0.214	0.138	0.393	0.214	0.138
75 %		0.197	0.107	0.069	0.197	0.107	0.069
90 %		0.079	0.043	0.028	0.079	0.043	0.028
None	R3 Stream	0.837	0.455	0.294	0.837	0.455	0.294
50 %		0.419	0.227	0.147	0.419	0.227	0.147
75 %		0.209	0.114	0.073	0.209	0.114	0.073
90 %		0.084	0.045	0.029	0.084	0.045	0.029
None	R4 Stream	0.592	0.322	0.208	0.592	0.322	0.208
50 %		0.296	0.161	0.104	0.296	0.161	0.104
75 %		0.148	0.080	0.066	0.148	0.080	0.052
90 %		0.066	0.066	0.066	0.059	0.032	0.021

Table 8.8-48: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to vines at application rate of 3 x 180 g a.s./ha, till BBCH 79 according to surface water Step 4 considering refined half-life on crop canopy

PEC_{sw} (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D6 Ditch	0.778	0.419	0.269	0.778	0.419	0.269
50 %		0.389	0.209	0.134	0.389	0.209	0.134
75 %		0.194	0.105	0.067	0.194	0.105	0.067
90 %		0.078	0.042	0.027	0.078	0.042	0.027
None	R1 Pond	0.128	0.086	0.064	0.127	0.086	0.063
50 %		0.064	0.043	0.032	0.064	0.043	0.032
75 %		0.032	0.022	0.016	0.032	0.022	0.016
90 %		0.013	0.009	0.007	0.013	0.009	0.006
None	R1 Stream	0.501	0.270	0.185	0.501	0.270	0.173
50 %		0.250	0.185	0.185	0.250	0.135	0.087
75 %		0.185	0.185	0.185	0.125	0.078	0.043
90 %		0.185	0.185	0.185	0.078	0.078	0.040
None	R2 Stream	0.671	0.362	0.232	0.671	0.362	0.232
50 %		0.335	0.181	0.116	0.335	0.181	0.116
75 %		0.168	0.090	0.058	0.168	0.090	0.058
90 %		0.067	0.036	0.023	0.067	0.036	0.023
None	R3 Stream	0.706	0.529	0.529	0.706	0.381	0.244
50 %		0.529	0.529	0.529	0.353	0.240	0.125
75 %		0.529	0.529	0.529	0.240	0.240	0.125
90 %		0.529	0.529	0.529	0.240	0.240	0.125
None	R4 Stream	0.501	0.339	0.339	0.501	0.270	0.173
50 %		0.339	0.339	0.339	0.250	0.152	0.087
75 %		0.339	0.339	0.339	0.152	0.152	0.079
90 %		0.339	0.339	0.339	0.152	0.152	0.079

Table 8.8-49: Global maximum PEC_{sw} values for Zoxamide following single application of GWN 10616 to vines at application rate of 1 x 180 g a.s./ha, till BBCH 79 according to surface water Step 4 considering refined half-life on crop canopy

PEC_{sw} (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D6 Ditch	0.676	0.367	0.237	0.676	0.367	0.237
50 %		0.338	0.184	0.119	0.338	0.184	0.119
75 %		0.169	0.092	0.059	0.169	0.092	0.059
90 %		0.068	0.037	0.024	0.068	0.037	0.024
None	R1 Pond	0.070	0.048	0.035	0.070	0.048	0.035
50 %		0.035	0.024	0.018	0.035	0.024	0.018
75 %		0.018	0.012	0.009	0.018	0.012	0.009
90 %		0.007	0.005	0.004	0.007	0.005	0.004
None	R1 Stream	0.581	0.316	0.204	0.581	0.316	0.204
50 %		0.291	0.158	0.102	0.291	0.158	0.102
75 %		0.145	0.079	0.051	0.145	0.079	0.051
90 %		0.058	0.032	0.020	0.058	0.032	0.020
None	R2 Stream	0.801	0.435	0.281	0.801	0.435	0.281
50 %		0.401	0.218	0.140	0.401	0.218	0.140
75 %		0.200	0.109	0.070	0.200	0.109	0.070
90 %		0.080	0.044	0.028	0.080	0.044	0.028
None	R3 Stream	0.842	0.458	0.295	0.842	0.458	0.295
50 %		0.421	0.229	0.170	0.421	0.229	0.148
75 %		0.211	0.170	0.170	0.211	0.114	0.074
90 %		0.170	0.170	0.170	0.084	0.076	0.040
None	R4 Stream	0.597	0.325	0.210	0.597	0.325	0.210
50 %		0.299	0.162	0.105	0.299	0.162	0.105
75 %		0.149	0.081	0.052	0.149	0.081	0.052
90 %		0.060	0.032	0.021	0.060	0.032	0.021

Table 8.8-50: Global maximum PEC$_{sw}$ values for Zoxamide following multiple application of GWN 10616 to pome fruit at application rate of 2 x 180 g a.s./ha, at BBCH 51 according to surface water Step 4 considering refined half-life on crop canopy

PEC$_{sw}$ (µg/L)	Scenario	STEP 4							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D3 Ditch	5.485	3.012	1.420	0.126	5.485	3.012	1.420	0.126
50 %		2.743	1.506	0.710	0.063	2.743	1.506	0.710	0.063
75 %		1.372	0.753	0.355	0.032	1.372	0.753	0.355	0.032
90 %		0.549	0.301	0.142	0.013	0.549	0.301	0.142	0.013
None	D4 Pond	0.771	0.404	0.232	0.034	0.771	0.404	0.232	0.034
50 %		0.385	0.202	0.116	0.017	0.385	0.202	0.116	0.017
75 %		0.192	0.101	0.058	0.009	0.192	0.101	0.058	0.009
90 %		0.077	0.040	0.023	0.003	0.077	0.040	0.023	0.003
None	D4 Stream	6.359	3.491	1.646	0.146	6.359	3.491	1.646	0.146
50 %		3.180	1.745	0.823	0.073	3.180	1.745	0.823	0.073
75 %		1.590	0.873	0.412	0.037	1.590	0.873	0.412	0.037
90 %		0.636	0.349	0.165	0.015	0.636	0.349	0.165	0.015
None	D5 Pond	0.850	0.446	0.256	0.038	0.850	0.446	0.256	0.038
50 %		0.425	0.223	0.128	0.019	0.425	0.223	0.128	0.019
75 %		0.212	0.111	0.064	0.009	0.212	0.111	0.064	0.009
90 %		0.085	0.045	0.026	0.004	0.085	0.045	0.026	0.004
None	D5 Stream	6.867	3.771	1.778	0.158	6.867	3.771	1.778	0.158
50 %		3.434	1.885	0.889	0.079	3.434	1.885	0.889	0.079
75 %		1.717	0.942	0.445	0.039	1.717	0.942	0.445	0.039
90 %		0.687	0.377	0.178	0.016	0.687	0.377	0.178	0.016
None	R1 Pond	0.851	0.446	0.256	0.038	0.851	0.446	0.256	0.038
50 %		0.425	0.223	0.128	0.019	0.425	0.223	0.128	0.019
75 %		0.212	0.112	0.064	0.011	0.212	0.112	0.064	0.009
90 %		0.085	0.045	0.026	0.006	0.085	0.045	0.026	0.004
None	R1 Stream	4.865	2.671	1.259	0.401	4.865	2.671	1.259	0.112

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4**							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
50 %		2.432	1.335	0.630	0.401	2.432	1.335	0.630	0.089
75 %		1.216	0.668	0.401	0.401	1.216	0.668	0.315	0.089
90 %		0.486	0.401	0.401	0.401	0.486	0.267	0.126	0.089
None	R2 Stream	6.519	3.579	1.688	0.339	6.519	3.579	1.688	0.150
50 %		3.260	1.789	0.844	0.339	3.260	1.789	0.844	0.079
75 %		1.630	0.895	0.422	0.339	1.630	0.895	0.422	0.079
90 %		0.652	0.358	0.339	0.339	0.652	0.358	0.169	0.079
None	R3 Stream	6.868	3.771	1.778	0.158	6.868	3.771	1.778	0.158
50 %		3.434	1.885	0.889	0.079	3.434	1.885	0.889	0.079
75 %		1.717	0.942	0.445	0.039	1.717	0.942	0.445	0.039
90 %		0.687	0.377	0.178	0.016	0.687	0.377	0.178	0.016
None	R4 Stream	4.863	2.670	1.259	1.097	4.863	2.670	1.259	0.237
50 %		2.432	1.335	1.097	1.097	2.432	1.335	0.630	0.237
75 %		1.216	1.097	1.097	1.097	1.216	0.667	0.315	0.237
90 %		1.097	1.097	1.097	1.097	0.486	0.464	0.237	0.237

Table 8.8-51: Global maximum PEC_{sw} values for Zoxamide following single application of GWN 10616 to pome fruit at application rate of 1 x 180 g a.s./ha, at BBCH 51 according to surface water Step 4 considering refined half-life on crop canopy

PEC_{sw} (µg/L)	Scenario	STEP 4							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D3 Ditch	6.752	3.037	1.544	0.174	6.752	3.037	1.544	0.174
50 %		3.376	1.519	0.772	0.087	3.376	1.519	0.772	0.087
75 %		1.688	0.759	0.386	0.044	1.688	0.759	0.386	0.044
90 %		0.675	0.304	0.154	0.017	0.675	0.304	0.154	0.017
None	D4 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.008	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.003	0.052	0.028	0.017	0.003
None	D4 Stream	7.514	3.381	1.718	0.194	7.514	3.381	1.718	0.194
50 %		3.757	1.690	0.859	0.097	3.757	1.690	0.859	0.097
75 %		1.878	0.845	0.429	0.049	1.878	0.845	0.429	0.049
90 %		0.751	0.338	0.172	0.019	0.751	0.338	0.172	0.019
None	D5 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.008	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.003	0.052	0.028	0.017	0.003
None	D5 Stream	8.009	3.604	1.831	0.207	8.009	3.604	1.831	0.207
50 %		4.004	1.801	0.915	0.103	4.004	1.801	0.915	0.103
75 %		2.002	0.900	0.458	0.052	2.002	0.900	0.458	0.052
90 %		0.801	0.360	0.183	0.021	0.801	0.360	0.183	0.021
None	R1 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.009	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.005	0.052	0.028	0.017	0.003

PEC_{sw} (µg/L)	Scenario	STEP 4							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	R1 Stream	5.995	2.698	1.371	0.303	5.995	2.698	1.371	0.155
50 %		2.998	1.348	0.685	0.303	2.998	1.348	0.685	0.077
75 %		1.499	0.674	0.343	0.303	1.499	0.674	0.343	0.067
90 %		0.600	0.303	0.303	0.303	0.600	0.270	0.137	0.067
None	R2 Stream	8.032	3.614	1.836	0.207	8.032	3.614	1.836	0.207
50 %		4.016	1.807	0.918	0.119	4.016	1.807	0.918	0.104
75 %		2.008	0.903	0.459	0.119	2.008	0.903	0.459	0.052
90 %		0.803	0.361	0.184	0.119	0.803	0.361	0.184	0.028
None	R3 Stream	8.404	3.782	1.921	0.217	8.404	3.782	1.921	0.217
50 %		4.202	1.890	0.961	0.109	4.202	1.890	0.961	0.109
75 %		2.101	0.945	0.480	0.054	2.101	0.945	0.480	0.054
90 %		0.840	0.378	0.192	0.022	0.840	0.378	0.192	0.022
None	R4 Stream	5.994	2.697	1.370	0.402	5.994	2.697	1.370	0.155
50 %		2.997	1.348	0.685	0.402	2.997	1.348	0.685	0.087
75 %		1.498	0.674	0.402	0.402	1.498	0.674	0.343	0.087
90 %		0.599	0.402	0.402	0.402	0.599	0.270	0.137	0.087

Table 8.8-52: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to pome fruit at application rate of 2 x 180 g a.s./ha, till BBCH 69 according to surface water Step 4 considering refined half-life on crop canopy

PEC_{sw} (µg/L)	Scenario	STEP 4 ZOPv1							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D3 Ditch	5.485	3.012	1.420	0.126	5.485	3.012	1.420	0.126
50 %		2.743	1.506	0.710	0.063	2.743	1.506	0.710	0.063
75 %		1.372	0.753	0.355	0.032	1.372	0.753	0.355	0.032
90 %		0.549	0.301	0.142	0.013	0.549	0.301	0.142	0.013
None	D4 Pond	0.894	0.469	0.269	0.040	0.894	0.469	0.269	0.040
50 %		0.447	0.235	0.135	0.020	0.447	0.235	0.135	0.020
75 %		0.223	0.117	0.067	0.010	0.223	0.117	0.067	0.010
90 %		0.089	0.047	0.027	0.004	0.089	0.047	0.027	0.004
None	D4 Stream	6.163	3.384	1.596	0.142	6.163	3.384	1.596	0.142
50 %		3.082	1.691	0.798	0.071	3.082	1.691	0.798	0.071
75 %		1.541	0.846	0.399	0.035	1.541	0.846	0.399	0.035
90 %		0.616	0.338	0.160	0.014	0.616	0.338	0.160	0.014
None	D5 Pond	0.847	0.444	0.255	0.038	0.847	0.444	0.255	0.038
50 %		0.423	0.222	0.128	0.019	0.423	0.222	0.128	0.019
75 %		0.211	0.111	0.064	0.009	0.211	0.111	0.064	0.009
90 %		0.084	0.044	0.025	0.004	0.084	0.044	0.025	0.004
None	D5 Stream	6.496	3.567	1.682	0.149	6.496	3.567	1.682	0.149
50 %		3.248	1.783	0.841	0.075	3.248	1.783	0.841	0.075
75 %		1.624	0.891	0.421	0.037	1.624	0.891	0.421	0.037
90 %		0.650	0.357	0.168	0.015	0.650	0.357	0.168	0.015
None	R1 Pond	0.851	0.446	0.256	0.038	0.851	0.446	0.256	0.038
50 %		0.425	0.223	0.128	0.019	0.425	0.223	0.128	0.019
75 %		0.212	0.112	0.064	0.011	0.212	0.112	0.064	0.009
90 %		0.085	0.045	0.026	0.006	0.085	0.045	0.026	0.004

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 ZOPv1							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	R1 Stream	4.865	2.671	1.259	0.401	4.865	2.671	1.259	0.112
50 %		2.432	1.335	0.630	0.401	2.432	1.335	0.630	0.089
75 %		1.216	0.668	0.401	0.401	1.216	0.668	0.315	0.089
90 %		0.486	0.401	0.401	0.401	0.486	0.267	0.126	0.089
None	R2 Stream	6.531	3.586	1.691	0.150	6.531	3.586	1.691	0.150
50 %		3.266	1.792	0.846	0.075	3.266	1.792	0.846	0.075
75 %		1.633	0.896	0.423	0.038	1.633	0.896	0.423	0.038
90 %		0.653	0.359	0.169	0.015	0.653	0.359	0.169	0.015
None	R3 Stream	6.840	3.756	1.771	0.157	6.840	3.756	1.771	0.157
50 %		3.420	1.877	0.886	0.079	3.420	1.877	0.886	0.079
75 %		1.710	0.939	0.443	0.039	1.710	0.939	0.443	0.039
90 %		0.684	0.376	0.177	0.016	0.684	0.376	0.177	0.016
None	R4 Stream	4.863	2.670	1.259	1.097	4.863	2.670	1.259	0.237
50 %		2.432	1.335	1.097	1.097	2.432	1.335	0.630	0.237
75 %		1.216	1.097	1.097	1.097	1.216	0.667	0.315	0.237
90 %		1.097	1.097	1.097	1.097	0.486	0.464	0.237	0.237

Table 8.8-53: Global maximum PEC$_{sw}$ values for Zoxamide following single application of GWN 10616 to pome fruit at application rate of 1 x 180 g a.s./ha, till BBCH 69 according to surface water Step 4 considering refined half-life on crop canopy

PEC$_{sw}$ (µg/L)	Scenario	STEP 4							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
None	D3 Ditch	6.762	3.041	1.546	0.175	6.762	3.041	1.546	0.175
50 %		3.381	1.521	0.773	0.087	3.381	1.521	0.773	0.087
75 %		1.690	0.760	0.387	0.044	1.690	0.760	0.387	0.044

PEC_{sw} (µg/L)	Scenario	STEP 4							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
90 %		0.676	0.304	0.155	0.017	0.676	0.304	0.155	0.017
None	D4 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.008	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.003	0.052	0.028	0.017	0.003
None	D4 Stream	7.569	3.406	1.730	0.195	7.569	3.406	1.730	0.195
50 %		3.784	1.702	0.865	0.098	3.784	1.702	0.865	0.098
75 %		1.892	0.851	0.433	0.049	1.892	0.851	0.433	0.049
90 %		0.757	0.341	0.173	0.020	0.757	0.341	0.173	0.020
None	D5 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.008	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.003	0.052	0.028	0.017	0.003
None	D5 Stream	8.009	3.604	1.831	0.207	8.009	3.604	1.831	0.207
50 %		4.004	1.801	0.915	0.103	4.004	1.801	0.915	0.103
75 %		2.002	0.900	0.458	0.052	2.002	0.900	0.458	0.052
90 %		0.801	0.360	0.183	0.021	0.801	0.360	0.183	0.021
None	R1 Pond	0.524	0.277	0.170	0.031	0.524	0.277	0.170	0.031
50 %		0.262	0.138	0.085	0.015	0.262	0.138	0.085	0.015
75 %		0.131	0.069	0.042	0.009	0.131	0.069	0.042	0.008
90 %		0.052	0.028	0.017	0.005	0.052	0.028	0.017	0.003
None	R1 Stream	5.995	2.698	1.371	0.303	5.995	2.698	1.371	0.155
50 %		2.998	1.348	0.685	0.303	2.998	1.348	0.685	0.077
75 %		1.499	0.674	0.343	0.303	1.499	0.674	0.343	0.067
90 %		0.600	0.303	0.303	0.303	0.600	0.270	0.137	0.067
None	R2 Stream	8.049	3.622	1.840	0.208	8.049	3.622	1.840	0.208
50 %		4.025	1.810	0.920	0.104	4.025	1.810	0.920	0.104
75 %		2.012	0.905	0.460	0.052	2.012	0.905	0.460	0.052

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	10	10	20	20
	No spray buffer (m)	10	15	20	50	10	15	20	50
90 %		0.805	0.362	0.184	0.021	0.805	0.362	0.184	0.021
None	R3 Stream	8.404	3.782	1.921	0.217	8.404	3.782	1.921	0.217
50 %		4.202	1.890	0.961	0.109	4.202	1.890	0.961	0.109
75 %		2.101	0.945	0.480	0.054	2.101	0.945	0.480	0.054
90 %		0.840	0.378	0.192	0.022	0.840	0.378	0.192	0.022
None	R4 Stream	5.870	2.641	1.342	0.678	5.870	2.641	1.342	0.152
50 %		2.935	1.320	0.678	0.678	2.935	1.320	0.671	0.146
75 %		1.467	0.678	0.678	0.678	1.467	0.660	0.335	0.146
90 %		0.678	0.678	0.678	0.678	0.587	0.287	0.146	0.146

Table 8.8-54: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, at BBCH 21 according to surface water Step 4 considering refined half-life on crop canopy

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.096	0.065	0.049	0.096	0.065	0.049
50 %		0.048	0.033	0.025	0.048	0.033	0.025
75 %		0.024	0.016	0.012	0.024	0.016	0.012
90 %		0.010	0.007	0.005	0.010	0.007	0.005
None	D4 Pond	0.037	0.030	0.025	0.037	0.030	0.025
50 %		0.019	0.015	0.012	0.019	0.015	0.012
75 %		0.009	0.007	0.006	0.009	0.007	0.006
90 %		0.004	0.003	0.002	0.004	0.003	0.002
None	D4 Stream	0.100	0.068	0.051	0.100	0.068	0.051
50 %		0.050	0.034	0.026	0.050	0.034	0.026

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
75 %		0.025	0.017	0.013	0.025	0.017	0.013
90 %		0.010	0.007	0.005	0.010	0.007	0.005
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.068	0.061	0.056	0.048	0.041	0.030
50 %		0.051	0.047	0.045	0.031	0.027	0.018
75 %		0.042	0.040	0.039	0.022	0.020	0.012
90 %		0.038	0.037	0.037	0.017	0.016	0.009
None	R1 Stream	0.540	0.540	0.540	0.245	0.245	0.129
50 %		0.540	0.540	0.540	0.245	0.245	0.129
75 %		0.540	0.540	0.540	0.245	0.245	0.129
90 %		0.540	0.540	0.540	0.245	0.245	0.129
None	R2 Stream	0.354	0.354	0.354	0.158	0.158	0.082
50 %		0.354	0.354	0.354	0.158	0.158	0.082
75 %		0.354	0.354	0.354	0.158	0.158	0.082
90 %		0.354	0.354	0.354	0.158	0.158	0.082
None	R3 Stream	0.695	0.695	0.695	0.315	0.315	0.165
50 %		0.695	0.695	0.695	0.315	0.315	0.165
75 %		0.695	0.695	0.695	0.315	0.315	0.165
90 %		0.695	0.695	0.695	0.315	0.315	0.165

* D6 not relevant for CEZ

Table 8.8-55: Global maximum PEC_{sw} values for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, at BBCH 21 according to surface water Step 4 considering refined half-life on crop canopy

PEC_{sw} (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
None	D3 Ditch	0.137	0.093	0.071	0.137	0.093	0.071
50 %		0.068	0.047	0.035	0.068	0.047	0.035
75 %		0.034	0.023	0.018	0.034	0.023	0.018
90 %		0.014	0.009	0.007	0.014	0.009	0.007
None	D4 Pond	0.020	0.016	0.014	0.020	0.016	0.014
50 %		0.010	0.008	0.007	0.010	0.008	0.007
75 %		0.005	0.004	0.003	0.005	0.004	0.003
90 %		0.002	0.002	0.001	0.002	0.002	0.001
None	D4 Stream	0.137	0.094	0.071	0.137	0.094	0.071
50 %		0.069	0.047	0.036	0.069	0.047	0.036
75 %		0.034	0.023	0.018	0.034	0.023	0.018
90 %		0.014	0.009	0.007	0.014	0.009	0.007
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.043	0.039	0.037	0.028	0.024	0.017
50 %		0.034	0.033	0.032	0.019	0.017	0.011
75 %		0.030	0.029	0.029	0.015	0.014	0.008
90 %		0.028	0.027	0.027	0.012	0.012	0.006
None	R1 Stream	0.399	0.399	0.399	0.181	0.181	0.095
50 %		0.399	0.399	0.399	0.181	0.181	0.095
75 %		0.399	0.399	0.399	0.181	0.181	0.095
90 %		0.399	0.399	0.399	0.181	0.181	0.095
None	R2 Stream	0.161	0.120	0.120	0.161	0.110	0.083

PEC$_{sw}$ (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
50 %		0.120	0.120	0.120	0.080	0.055	0.042
75 %		0.120	0.120	0.120	0.054	0.054	0.028
90 %		0.120	0.120	0.120	0.054	0.054	0.028
None	R3 Stream	0.171	0.118	0.118	0.171	0.117	0.089
50 %		0.118	0.118	0.118	0.086	0.058	0.045
75 %		0.118	0.118	0.118	0.053	0.053	0.028
90 %		0.118	0.118	0.118	0.053	0.053	0.028

*D6 not relevant for CEZ

~~**Table 8.8-56: Global maximum PEC_{sw} values for Zoxamide following multiple application of GWN 10616 to potatoes at application rate of 3 x 150 g a.s./ha, till BBCH 89 according to surface water Step 4 considering refined half-life on crop canopy**~~

~~PEC$_{sw}$ (µg/L)~~	~~Scenario~~	~~STEP 4~~					
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~None~~	~~None~~	~~None~~	~~10~~	~~10~~	~~20~~
	~~No spray buffer (m)~~	~~10~~	~~15~~	~~20~~	~~10~~	~~15~~	~~20~~
~~None~~	~~D3 Ditch~~	~~0.096~~	~~0.065~~	~~0.049~~	~~0.096~~	~~0.065~~	~~0.049~~
~~50 %~~		~~0.048~~	~~0.033~~	~~0.025~~	~~0.048~~	~~0.033~~	~~0.025~~
~~75 %~~		~~0.024~~	~~0.016~~	~~0.012~~	~~0.024~~	~~0.016~~	~~0.012~~
~~90 %~~		~~0.010~~	~~0.007~~	~~0.005~~	~~0.010~~	~~0.007~~	~~0.005~~
~~None~~	~~D4 Pond~~	~~0.037~~	~~0.029~~	~~0.024~~	~~0.037~~	~~0.029~~	~~0.024~~
~~50 %~~		~~0.018~~	~~0.015~~	~~0.012~~	~~0.018~~	~~0.015~~	~~0.012~~
~~75 %~~		~~0.009~~	~~0.007~~	~~0.006~~	~~0.009~~	~~0.007~~	~~0.006~~
~~90 %~~		~~0.004~~	~~0.003~~	~~0.003~~	~~0.004~~	~~0.003~~	~~0.003~~
~~None~~	~~D4 Stream~~	~~0.105~~	~~0.071~~	~~0.054~~	~~0.105~~	~~0.071~~	~~0.054~~
~~50 %~~		~~0.052~~	~~0.035~~	~~0.027~~	~~0.052~~	~~0.035~~	~~0.027~~
~~75 %~~		~~0.026~~	~~0.018~~	~~0.013~~	~~0.026~~	~~0.018~~	~~0.013~~
~~90 %~~		~~0.011~~	~~0.011~~	~~0.011~~	~~0.011~~	~~0.011~~	~~0.011~~
~~None~~	~~D6 Ditch 1st crop~~	~~*~~	~~*~~	~~*~~	~~*~~	~~*~~	~~*~~
~~None~~	~~D6 Ditch 2nd crop~~	~~*~~	~~*~~	~~*~~	~~*~~	~~*~~	~~*~~
~~None~~	~~R1 Pond~~	~~0.032~~	~~0.026~~	~~0.021~~	~~0.032~~	~~0.026~~	~~0.021~~
~~50 %~~		~~0.016~~	~~0.013~~	~~0.011~~	~~0.016~~	~~0.013~~	~~0.011~~
~~75 %~~		~~0.008~~	~~0.006~~	~~0.005~~	~~0.008~~	~~0.006~~	~~0.005~~
~~90 %~~		~~0.003~~	~~0.003~~	~~0.003~~	~~0.003~~	~~0.003~~	~~0.002~~
~~None~~	~~R1 Stream~~	~~0.086~~	~~0.058~~	~~0.044~~	~~0.086~~	~~0.058~~	~~0.044~~
~~50 %~~		~~0.043~~	~~0.038~~	~~0.038~~	~~0.043~~	~~0.029~~	~~0.022~~
~~75 %~~		~~0.038~~	~~0.038~~	~~0.038~~	~~0.021~~	~~0.017~~	~~0.011~~
~~90 %~~		~~0.038~~	~~0.038~~	~~0.038~~	~~0.017~~	~~0.017~~	~~0.009~~
~~None~~	~~R2 Stream~~	~~0.251~~	~~0.251~~	~~0.251~~	~~0.115~~	~~0.112~~	~~0.059~~

~~PEC_{sw} (µg/L)~~	~~Scenario~~	~~STEP 4~~					
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~None~~	~~None~~	~~None~~	~~10~~	~~10~~	~~20~~
	~~No spray buffer (m)~~	~~10~~	~~15~~	~~20~~	~~10~~	~~15~~	~~20~~
~~50 %~~		~~0.251~~	~~0.251~~	~~0.251~~	~~0.112~~	~~0.112~~	~~0.058~~
~~75 %~~		~~0.251~~	~~0.251~~	~~0.251~~	~~0.112~~	~~0.112~~	~~0.058~~
~~90 %~~		~~0.251~~	~~0.251~~	~~0.251~~	~~0.112~~	~~0.112~~	~~0.058~~
~~None~~	~~R3 Stream~~	~~0.423~~	~~0.423~~	~~0.423~~	~~0.193~~	~~0.193~~	~~0.101~~
~~50 %~~		~~0.423~~	~~0.423~~	~~0.423~~	~~0.193~~	~~0.193~~	~~0.101~~
~~75 %~~		~~0.423~~	~~0.423~~	~~0.423~~	~~0.193~~	~~0.193~~	~~0.101~~
~~90 %~~		~~0.423~~	~~0.423~~	~~0.423~~	~~0.193~~	~~0.193~~	~~0.101~~

~~*D6 not relevant for CEZ~~

~~Table 8.8-57: Global maximum PEC_{sw} values for Zoxamide following single application of GWN 10616 to potatoes at application rate of 1 x 150 g a.s./ha, till BBCH 89 according to surface water Step 4 considering refined half-life on crop canopy~~

~~PEC_{sw} (µg/L)~~	~~Scenario~~	~~STEP 4~~					
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~None~~	~~None~~	~~None~~	~~10~~	~~10~~	~~20~~
	~~No spray buffer (m)~~	~~10~~	~~15~~	~~20~~	~~10~~	~~15~~	~~20~~
~~None~~	~~D3 Ditch~~	~~0.137~~	~~0.093~~	~~0.071~~	~~0.137~~	~~0.093~~	~~0.071~~
~~50 %~~		~~0.068~~	~~0.047~~	~~0.036~~	~~0.068~~	~~0.047~~	~~0.036~~
~~75 %~~		~~0.034~~	~~0.023~~	~~0.018~~	~~0.034~~	~~0.023~~	~~0.018~~
~~90 %~~		~~0.014~~	~~0.009~~	~~0.007~~	~~0.014~~	~~0.009~~	~~0.007~~
~~None~~	~~D4 Pond~~	~~0.020~~	~~0.016~~	~~0.014~~	~~0.020~~	~~0.016~~	~~0.014~~
~~50 %~~		~~0.010~~	~~0.008~~	~~0.007~~	~~0.010~~	~~0.008~~	~~0.007~~
~~75 %~~		~~0.005~~	~~0.004~~	~~0.003~~	~~0.005~~	~~0.004~~	~~0.003~~
~~90 %~~		~~0.002~~	~~0.002~~	~~0.001~~	~~0.002~~	~~0.002~~	~~0.001~~
~~None~~	~~D4 Stream~~	~~0.132~~	~~0.090~~	~~0.069~~	~~0.132~~	~~0.090~~	~~0.069~~
~~50 %~~		~~0.066~~	~~0.045~~	~~0.034~~	~~0.066~~	~~0.045~~	~~0.034~~
~~75 %~~		~~0.033~~	~~0.023~~	~~0.017~~	~~0.033~~	~~0.023~~	~~0.017~~

PEC_{sw} (µg/L)	Scenario	STEP 4					
Nozzle reduction	Vegetative strip (m)	None	None	None	10	10	20
	No spray buffer (m)	10	15	20	10	15	20
90 %		0.013	0.009	0.007	0.013	0.009	0.007
None	D6 Ditch 1st crop	*	*	*	*	*	*
None	D6 Ditch 2nd crop	*	*	*	*	*	*
None	R1 Pond	0.020	0.016	0.014	0.020	0.016	0.014
50 %		0.010	0.008	0.007	0.010	0.008	0.007
75 %		0.005	0.004	0.003	0.005	0.004	0.003
90 %		0.002	0.002	0.002	0.002	0.002	0.001
None	R1 Stream	0.122	0.083	0.063	0.122	0.083	0.063
50 %		0.061	0.042	0.032	0.061	0.042	0.032
75 %		0.030	0.030	0.030	0.030	0.021	0.016
90 %		0.030	0.030	0.030	0.014	0.014	0.007
None	R2 Stream	0.206	0.206	0.206	0.163	0.112	0.085
50 %		0.206	0.206	0.206	0.092	0.092	0.048
75 %		0.206	0.206	0.206	0.092	0.092	0.048
90 %		0.206	0.206	0.206	0.092	0.092	0.048
None	R3 Stream	0.278	0.278	0.278	0.172	0.127	0.089
50 %		0.278	0.278	0.278	0.127	0.127	0.066
75 %		0.278	0.278	0.278	0.127	0.127	0.066
90 %		0.278	0.278	0.278	0.127	0.127	0.066

*D6 not relevant for CEZ

Metabolites of Zoxamide

Metabolite RH-127450

Table 8.8-~~58~~42: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-127450 following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		54.2	50.4	291.0
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	2.3	2.1	12.5
	June - Sep.	minimal (40 %)	2.3	2.1	12.5
South Europe	Mar. - May	minimal (40 %)	3.5	3.2	19.5
	June - Sep.	minimal (40 %)	2.9	2.6	16.0
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	4.5	4.0	24.3
	June - Sep.	minimal (40 %)	4.5	4.0	24.3
South Europe	Mar. - May	minimal (40 %)	6.3	5.7	34.7
	June - Sep.	minimal (40 %)	5.4	4.8	29.5

Table 8.8-~~59~~43: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-127450 following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		54.2	50.4	291.0
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	1.9	1.7	10.2
	June - Sep.	full canopy (60 %)	1.9	1.7	10.2
South Europe	Mar. - May	full canopy (60 %)	2.6	2.4	14.8
	June - Sep.	full canopy (60 %)	2.3	2.1	12.5
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	3.9	3.4	20.9
	June - Sep.	full canopy (60 %)	3.9	3.4	20.9
South Europe	Mar. - May	full canopy (60 %)	5.1	4.6	27.8
	June - Sep.	full canopy (60 %)	4.5	4.0	24.3

Table 8.8-~~60~~44: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-127450 following multiple application of GWN 10616 to pome fruit with application rate 180 g Zoxamide /ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		45.1	38.6	194.0
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	6.2	4.1	24.2
	June - Sep.	full canopy (65 %)	6.2	4.1	24.2
South Europe	Mar. - May	full canopy (65 %)	6.2	4.7	28.3
	June - Sep.	full canopy (65 %)	6.2	4.4	26.3
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	8.9	6.9	40.9
	June - Sep.	full canopy (65 %)	8.9	6.9	40.9
South Europe	Mar. - May	full canopy (65 %)	8.9	7.7	46.8
	June - Sep.	full canopy (65 %)	8.9	7.3	43.9

Table 8.8-~~61~~45: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-127450 following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		42.4	40.5	242.5
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	1.1	1.1	6.4
	June - Sep.	average (50 %)	1.1	1.1	6.4
South Europe	Mar. - May	average (50 %)	1.9	1.8	11.2
	June - Sep.	average (50 %)	1.5	1.5	8.8
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	2.0	1.8	11.0
	June - Sep.	average (50 %)	2.0	1.8	11.0
South Europe	Mar. - May	average (50 %)	3.3	3.1	18.6
	June - Sep.	average (50 %)	2.6	2.4	18.8

Table 8.8-~~62~~46: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-127450 following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		42.4	40.5	242.5
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	0.8	0.7	4.5
	June - Sep.	full canopy (70 %)	0.8	0.7	4.5
South Europe	Mar. - May	full canopy (70 %)	1.3	1.2	7.4
	June - Sep.	full canopy (70 %)	1.1	1.0	5.9
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	1.5	1.3	8.0
	June - Sep.	full canopy (70 %)	1.5	1.3	8.0
South Europe	Mar. - May	full canopy (70 %)	2.2	2.1	12.6
	June - Sep.	full canopy (70 %)	1.8	1.7	10.3

Metabolite RH-24549

Table 8.8-~~63~~47: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-24549 following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		38.4	38.1	34.7
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	1.1	1.1	1.0
	June - Sep.	minimal (40 %)			
South Europe	Mar. - May	minimal (40 %)	2.1	2.1	1.9
	June - Sep.	minimal (40 %)	1.6	1.6	1.5
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	2.0	1.9	1.8
	June - Sep.	minimal (40 %)	2.0	1.9	1.8
South Europe	Mar. - May	minimal (40 %)	3.6	3.6	3.2
	June - Sep.	minimal (40 %)	2.8	2.7	2.5

Table 8.8-6448: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-24549 following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		38.4	38.1	34.7
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	0.8	0.8	0.7
	June - Sep.	full canopy (60 %)	0.8	0.8	0.7
South Europe	Mar. - May	full canopy (60 %)	1.5	1..5	1.4
	June - Sep.	full canopy (60 %)	1.1	1.1	1.0
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	1.4	1.4	1.3
	June - Sep.	full canopy (60 %)	1.4	1.4	1.3
South Europe	Mar. - May	full canopy (60 %)	2.5	2.5	2.3
	June - Sep.	full canopy (60 %)	2.0	1.9	1.8

Table 8.8-6549: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-24549 following multiple application of GWN 10616 to pome fruit with application rate 180 g Zoxamide /ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		26.4	26.1	22.9
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	1.1	1.1	0.9
	June - Sep.	full canopy (65 %)	1.1	1.1	0.9
South Europe	Mar. - May	full canopy (65 %)	1.7	1.6	1.5
	June - Sep.	full canopy (65 %)	1.4	1.3	1.2
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	1.8	1.7	1.6
	June - Sep.	full canopy (65 %)	1.8	1.7	1.6
South Europe	Mar. - May	full canopy (65 %)	2.7	2.6	2.4
	June - Sep.	full canopy (65 %)	2.2	2.2	2.0

Table 8.8-6650: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-24549 following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		31.7	31.5	28.7
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	0.7	0.7	0.7
	June - Sep.	average (50 %)	0.7	0.7	0.7
South Europe	Mar. - May	average (50 %)	1.4	1.4	1.3
	June - Sep.	average (50 %)	1.1	1.1	1.0
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	1.3	1.3	1.2
	June - Sep.	average (50 %)	1.3	1.3	1.2
South Europe	Mar. - May	average (50 %)	2.5	2.4	2.2
	June - Sep.	average (50 %)	1.9	1.9	1.7

Table 8.8-6751: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-24549 following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		31.7	31.5	28.7
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	0.5	0.5	0.4
	June - Sep.	full canopy (70 %)	0.5	0.5	0.4
South Europe	Mar. - May	full canopy (70 %)	0.9	0.9	0.8
	June - Sep.	full canopy (70 %)	0.7	0.7	0.6
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	0.8	0.8	0.7
	June - Sep.	full canopy (70 %)	0.8	0.8	0.7
South Europe	Mar. - May	full canopy (70 %)	1.5	1.5	1.4
	June - Sep.	full canopy (70 %)	1.2	1.1	1.0

Metabolite RH-163353

Table 8.8-6852: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-163353 following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		60.9	60.3	38.9
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	2.5	2.4	1.7
	June - Sep.	minimal (40 %)	2.5	2.4	1.7
South Europe	Mar. - May	minimal (40 %)	4.1	4.0	2.7
	June - Sep.	minimal (40 %)	3.3	3.2	2.2
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	5.1	5.0	3.3
	June - Sep.	minimal (40 %)	5.1	5.0	3.3
South Europe	Mar. - May	minimal (40 %)	7.7	7.6	5.1
	June - Sep.	minimal (40 %)	6.4	6.3	4.2

Table 8.8-6953: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-163353 following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		60.9	60.3	38.9
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	2.0	1.9	1.3
	June - Sep.	full canopy (60 %)	2.0	1.9	1.3
South Europe	Mar. - May	full canopy (60 %)	3.0	3.0	2.0
	June - Sep.	full canopy (60 %)	2.5	2.4	1.7
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	4.2	4.1	2.7
	June - Sep.	full canopy (60 %)	4.2	4.1	2.7
South Europe	Mar. - May	full canopy (60 %)	6.0	5.9	3.9
	June - Sep.	full canopy (60 %)	5.1	5.0	3.3

Table 8.8-~~70~~54: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-163353 following multiple application of GWN 10616 to pome fruit with application rate 180 g Zoxamide /ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		45.8	44.9	25.9
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	4.3	4.1	2.8
	June - Sep.	full canopy (65 %)	4.3	4.1	2.8
South Europe	Mar. - May	full canopy (65 %)	5.2	5.1	3.4
	June - Sep.	full canopy (65 %)	4.7	4.6	3.1
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	7.3	7.1	4.8
	June - Sep.	full canopy (65 %)	7.3	7.1	4.8
South Europe	Mar. - May	full canopy (65 %)	8.7	8.5	5.7
	June - Sep.	full canopy (65 %)	8.0	7.8	5.3

Table 8.8-~~71~~55: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-163353 following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		49.2	48.8	32.9
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	1.4	1.3	0.9
	June - Sep.	average (50 %)	1.4	1.3	0.9
South Europe	Mar. - May	average (50 %)	2.4	2.4	1.6
	June - Sep.	average (50 %)	1.9	1.9	1.3
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	2.6	2.5	1.7
	June - Sep.	average (50 %)	2.6	2.5	1.7
South Europe	Mar. - May	average (50 %)	4.5	4.5	3.0
	June - Sep.	average (50 %)	3.5	3.5	2.4

Table 8.8-~~72~~56: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-163353 following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		49.2	48.8	32.9
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	0.9	0.9	0.6
	June - Sep.	full canopy (70 %)	0.9	0.9	0.6
South Europe	Mar. - May	full canopy (70 %)	1.6	1.5	1.1
	June - Sep.	full canopy (70 %)	1.2	1.2	0.8
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	1.8	1.7	1.2
	June - Sep.	full canopy (70 %)	1.8	1.7	1.2
South Europe	Mar. - May	full canopy (70 %)	2.9	2.9	2.0
	June - Sep.	full canopy (70 %)	2.3	2.3	1.6

Metabolite RH-141455

Table 8.8-~~73~~57: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-141455 following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		13.4	13.3	0.4
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	0.4	0.4	0.01
	June - Sep.	minimal (40 %)	0.4	0.4	0.01
South Europe	Mar. - May	minimal (40 %)	0.8	0.8	0.02
	June - Sep.	minimal (40 %)	0.6	0.6	0.02
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	0.8	0.8	0.02
	June - Sep.	minimal (40 %)	0.8	0.8	0.02
South Europe	Mar. - May	minimal (40 %)	1.4	1.3	0.04
	June - Sep.	minimal (40 %)	1.1	1.1	0.03

Table 8.8-7458: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-141455 following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		13.4	13.3	0.4
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	0.3	0.3	0.01
	June - Sep.	full canopy (60 %)	0.3	0.3	0.01
South Europe	Mar. - May	full canopy (60 %)	0.5	0.5	0.02
	June - Sep.	full canopy (60 %)	0.4	0.4	0.02
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	0.6	0.5	0.02
	June - Sep.	full canopy (60 %)	0.6	0.6	0.02
South Europe	Mar. - May	full canopy (60 %)	1.0	1.0	0.03
	June - Sep.	full canopy (60 %)	0.8	0.8	0.02

Table 8.8-7559: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-141455 following multiple application of GWN 10616 to pome fruit with application rate 180 g Zoxamide /ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		9.3	9.2	0.2
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	0.5	0.5	0.01
	June - Sep.	full canopy (65 %)	0.5	0.5	0.01
South Europe	Mar. - May	full canopy (65 %)	0.7	0.7	0.02
	June - Sep.	full canopy (65 %)	0.6	0.6	0.02
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	0.8	0.8	0.02
	June - Sep.	full canopy (65 %)	0.8	0.8	0.02
South Europe	Mar. - May	full canopy (65 %)	1.1	1.1	0.03
	June - Sep.	full canopy (65 %)	0.9	0.9	0.03

Table 8.8-~~76~~60: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-141455 following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		11.0	10.9	0.3
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	0.3	0.3	0.01
	June - Sep.	average (50 %)	0.3	0.3	0.01
South Europe	Mar. - May	average (50 %)	0.5	0.5	0.01
	June - Sep.	average (50 %)	0.4	0.4	0.01
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	0.5	0.5	0.01
	June - Sep.	average (50 %)	0.5	0.5	0.01
South Europe	Mar. - May	average (50 %)	0.9	0.9	0.03
	June - Sep.	average (50 %)	0.7	0.7	0.02

Table 8.8-~~77~~61: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-141455 following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		11.0	10.9	0.3
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	0.2	0.2	0.005
	June - Sep.	full canopy (70 %)	0.2	0.2	0.005
South Europe	Mar. - May	full canopy (70 %)	0.3	0.3	0.01
	June - Sep.	full canopy (70 %)	0.2	0.2	0.01
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	0.3	0.3	0.01
	June - Sep.	full canopy (70 %)	0.3	0.3	0.01
South Europe	Mar. - May	full canopy (70 %)	0.6	0.6	0.02
	June - Sep.	full canopy (70 %)	0.4	0.4	0.01

Metabolite RH-139432

Table 8.8-7862: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-139432 following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		30.2	29.9	3.0
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	1.4	1.4	0.14
	June - Sep.	minimal (40 %)	1.4	1.4	0.14
South Europe	Mar. - May	minimal (40 %)	2.2	2.1	0.2
	June - Sep.	minimal (40 %)	1.8	1.8	0.2
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	3.0	3.0	0.3
	June - Sep.	minimal (40 %)	3.0	3.0	0.3
South Europe	Mar. - May	minimal (40 %)	4.5	4.5	0.4
	June - Sep.	minimal (40 %)	3.8	3.7	0.4

Table 8.8-7963: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-139432 following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		30.2	29.9	3.0
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	1.1	1.1	0.1
	June - Sep.	full canopy (60 %)	1.1	1.1	0.1
South Europe	Mar. - May	full canopy (60 %)	1.4	1.4	0.1
	June - Sep.	full canopy (60 %)	1.6	1.6	0.2
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	2.6	2.5	0.3
	June - Sep.	full canopy (60 %)	2.6	2.5	0.3
South Europe	Mar. - May	full canopy (60 %)	3.0	3.0	0.3
	June - Sep.	full canopy (60 %)	3.5	3.5	0.4

Table 8.8-~~80~~64: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-139432 following multiple application of GWN 10616 to pome fruit with application rate 180 g Zoxamide /ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		23.4	23.2	2.3
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	2.7	2.6	0.3
	June - Sep.	full canopy (65 %)	2.7	2.6	0.3
South Europe	Mar. - May	full canopy (65 %)	3.1	3.1	0.3
	June - Sep.	full canopy (65 %)	2.9	2.9	0.3
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	4.6	4.6	0.5
	June - Sep.	full canopy (65 %)	4.6	4.6	0.5
South Europe	Mar. - May	full canopy (65 %)	5.4	5.3	0.5
	June - Sep.	full canopy (65 %)	5.0	5.0	0.5

Table 8.8-~~81~~65: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-139432 following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		24.1	24.0	2.4
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	0.7	0.7	0.1
	June - Sep.	average (50 %)	0.7	0.2	0.1
South Europe	Mar. - May	average (50 %)	1.2	1.2	0.1
	June - Sep.	average (50 %)	1.0	1.0	0.1
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	1.4	1.4	0.1
	June - Sep.	average (50 %)	1.4	1.4	0.1
South Europe	Mar. - May	average (50 %)	2.5	2.5	0.3
	June - Sep.	average (50 %)	2.0	1.9	0.2

Table 8.8-8266: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for RH-139432 following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PECsed (µg/kg)
Step 1	---		24.1	24.0	2.4
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	0.5	0.5	0.1
	June - Sep.	full canopy (70 %)	0.5	0.5	0.1
South Europe	Mar. - May	full canopy (70 %)	0.8	0.8	0.1
	June - Sep.	full canopy (70 %)	0.7	0.7	0.1
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	1.1	1.0	0.1
	June - Sep.	full canopy (70 %)			
South Europe	Mar. - May	full canopy (70 %)	1.6	1.6	0.2
	June - Sep.	full canopy (70 %)	1.3	1.3	0.1

No Step 3 calculations were performed for metabolites of Zoxamide.

No Step 4 calculations were performed for metabolites of Zoxamide.

Phosphonic acid and Phosphate ions

Table 8.8-~~83~~67: Input parameters related to active substance Phosphonic acid and Phosphate ions for $PEC_{sw/sed}$ calculations STEP 1/2

Compound	Phosphonic acid	Phosphate ions	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	80.5	94.9	Y [1]
Water solubility (mg/L)	1875000 (25°C) 1557100 (20°C)	1875000 (25°C) 1557100 (20°C)	Y [1]
K_f (mL/g)	8.73/10 000 (two sets of simulations)[2]	10/10 000 (two sets of simulations)	Y [1] geomean
Freundlich Exponent 1/n	0.9	-	Y [1]
$DT_{50,soil}$ (d)	196	1000	Y [1]/Default
$DT_{50,water}$ (d)	1000	1000	Y [1]/Default
$DT_{50,sed}$ (d)	1000	1000	Y [1]/Default
$DT_{50,whole\ system}$ (d)	1000	1000	Y [1]/Default
Maximum occurrence observed (% molar basis with respect to the parent)	-	-	Y [1]
Formation fraction in soil:	-	-	Y [1]

[1] EFSA conclusion on the peer review of the active substance Potassium phosphonates EFSA (2012)
[2] In modelling the Phosphonic acid with lower K_f is assigned as PA_lowKoc , Phosphonic acid with higher K_f is assigned as PA_HighKoc, Phosphate ions with lower K_f are assigned as PI_lowKoc , Phosphate ions with higher K_f assigned as PI_HighKoc

Table 8.8-~~84~~68: The application rate of Phosphate ions based on Phosphonic acid application rates

Use assessed	1	3	5
	Application rate (g/ha)		
Phosphonic acid	1500	1500	1250
Phosphate ions	1768	1768.3	1474

$PEC_{sw/sed}$ of Phosphonic acid (PA)

Table 8.8-8569: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_HighK_{oc} following multiple application GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		225.1	114.9	1.13E+4
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	40.14	8.093	691.5
	June - Sep.	minimal (40 %)	40.14	8.093	691.5
South Europe	Mar. - May	minimal (40 %)	40.14	11.51	1100
	June - Sep.	minimal (40 %)	40.14	9.803	897.7
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	41.41	19.19	1920
	June - Sep.	minimal (40 %)	41.41	19.19	1920
South Europe	Mar. - May	minimal (40 %)	41.41	29.16	3120
	June - Sep.	minimal (40 %)	41.41	24.18	2520

Table 8.8-8670: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_lowK_{oc} following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1600	1590	136.9
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	98.20	97.34	8.553
	June - Sep.	minimal (40 %)	98.20	97.34	8.553
South Europe	Mar. - May	minimal (40 %)	156.7	155.4	13.65
	June - Sep.	minimal (40 %)	127.4	126.4	11.10
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	272.4	270.1	23.73
	June - Sep.	minimal (40 %)	272.4	270.1	23.73
South Europe	Mar. - May	minimal (40 %)	443.0	439.4	38.61
	June - Sep.	minimal (40 %)	357.7	354.7	31.17

Table 8.8-~~87~~71: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_HighK_{oc} following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		225.1	114.9	1.13E+4
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	40.14	6.953	554.0
	June - Sep.	full canopy (60 %)	40.14	6.953	554.0
South Europe	Mar. - May	full canopy (60 %)	40.14	9.233	829.0
	June - Sep.	full canopy (60 %)	40.14	8.093	691.5
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	41.41	15.86	1520
	June - Sep.	full canopy (60 %)	41.41	15.86	1520
South Europe	Mar. - May	full canopy (60 %)	41.41	22.51	2320
	June - Sep.	full canopy (60 %)	41.41	19.19	1920

Table 8.8-~~88~~72: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_LowK_{oc} following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1600	1590	139.7
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	78.71	77.99	6.853
	June - Sep.	full canopy (60 %)	78.71	77.99	6.853
South Europe	Mar. - May	full canopy (60 %)	117.7	116.7	10.25
	June - Sep.	full canopy (60 %)	98.20	97.34	8.553
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	215.5	213.6	18.77
	June - Sep.	full canopy (60 %)	215.5	213.6	18.77
South Europe	Mar. - May	full canopy (60 %)	329.3	326.5	28.69
	June - Sep.	full canopy (60 %)	272.4	270.1	23.73

Table 8.8-~~89~~73: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_HighK_{oc} following multiple application of GWN 10616 to pome fruit with application rate 1500 g PA/ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		361.7	95.95	9010
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	146.0	18.99	1260
	June - Sep.	full canopy (65 %)	146.0	18.99	1260
South Europe	Mar. - May	full canopy (65 %)	146.0	20.98	1500
	June - Sep.	full canopy (65 %)	146.0	19.99	1380
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	140.6	28.47	2250
	June - Sep.	full canopy (65 %)	140.6	28.47	2250
South Europe	Mar. - May	full canopy (65 %)	140.6	32.42	2720
	June - Sep.	full canopy (65 %)	140.6	30.45	2490

Table 8.8-~~90~~74: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_lowK_{oc} following multiple application of GWN 10616 to pome fruit with application rate 1500 g PA/ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1280	1270	111.41
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	178.6	176.7	15.53
	June - Sep.	full canopy (65 %)	178.6	176.7	15.53
South Europe	Mar. - May	full canopy (65 %)	212.7	210.6	18.51
	June - Sep.	full canopy (65 %)	195.6	193.7	17.02
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	319.6	316.4	27.80
	June - Sep.	full canopy (65 %)	319.6	316.4	27.80
South Europe	Mar. - May	full canopy (65 %)	387.1	383.4	33.69
	June - Sep.	full canopy (65 %)	353.4	349.9	30.74

Table 8.8-~~91~~75: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_HighK_{oc} following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		121.7	89.73	8960
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	11.50	3.713	366.3
	June - Sep.	average (50 %)	11.50	3.713	366.3
South Europe	Mar. - May	average (50 %)	11.50	6.088	652.8
	June - Sep.	average (50 %)	11.50	4.901	509.5
Step 2 - multiple application					
North Europe	Mar. - May	average 50 %)	11.00	10.09	1010
	June - Sep.	average (50 %)	11.00	10.09	1010
South Europe	Mar. - May	average (50 %)	19.39	18.42	1850
	June - Sep.	average (50 %)	15.19	14.25	1430

Table 8.8-~~92~~76: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_lowK_{oc} following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1270	1260	110.8
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	51.98	51.57	4.531
	June - Sep.	average (50 %)	51.98	51.57	4.531
South Europe	Mar. - May	average (50 %)	92.59	91.88	8.074
	June - Sep.	average (50 %)	72.29	71.72	6.303
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	143.8	142.7	12.54
	June - Sep.	average (50 %)	143.8	142.7	12.54
South Europe	Mar. - May	average (50 %)	262.7	260.7	22.91
	June - Sep.	average (50 %)	203.2	201.7	17.72

Table 8.8-9377: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_HighK_{oc} following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		121.7	89.73	8960
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	11.50	2.763	251.8
	June - Sep.	full canopy (70 %)	11.50	2.763	251.8
South Europe	Mar. - May	full canopy (70 %)	11.50	4.188	423.6
	June - Sep.	full canopy (70 %)	11.50	3.476	337.7
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	10.13	6.425	678.1
	June - Sep.	full canopy (70 %)	10.13	6.425	678.1
South Europe	Mar. - May	full canopy (70 %)	12.68	11.75	1180
	June - Sep.	full canopy (70 %)	10.16	9.256	929.6

Table 8.8-9478: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PA_lowK_{oc} following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1270	1260	110.8
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	35.74	35.44	3.114
	June - Sep.	full canopy (70 %)	35.74	35.44	3.114
South Europe	Mar. - May	full canopy (70 %)	60.11	59.63	5.240
	June - Sep.	full canopy (70 %)	47.92	47.53	4.177
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	96.24	95.45	8.387
	June - Sep.	full canopy (70 %)	96.24	95.45	8.387
South Europe	Mar. - May	full canopy (70 %)	167.6	166.3	14.61
	June - Sep.	full canopy (70 %)	131.9	130.9	11.50

No Step 3 calculations were performed for Phosphonic acid.

No Step 4 calculations were performed for Phosphonic acid.

$PEC_{sw/sed}$ of Phosphate ions (PI)

Table 8.8-~~95~~79: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_highK_{oc} following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		265.3	135.4	1.23E+4
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	47.31	9.585	820.6
	June - Sep.	minimal (40 %)	47.31	9.585	820.6
South Europe	Mar. - May	minimal (40 %)	47.31	13.66	1310
	June - Sep.	minimal (40 %)	47.31	11.62	1070
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	48.81	23.02	2310
	June - Sep.	minimal (40 %)	48.81	23.02	2310
South Europe	Mar. - May	minimal (40 %)	48.81	35.18	3780
	June - Sep.	minimal (40 %)	48.81	29.10	3040

Table 8.8-~~96~~80: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_lowK_{oc} following multiple application of GWN 10616 to vines BBCH 14

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1890	1870	174.5
Step 2 - single application					
North Europe	Mar. - May	minimal (40 %)	116.4	115.3	11.61
	June - Sep.	minimal (40 %)	116.4	115.3	11.61
South Europe	Mar. - May	minimal (40 %)	186.0	184.4	18.56
	June - Sep.	minimal (40 %)	151.2	149.9	15.09
Step 2 - multiple application					
North Europe	Mar. - May	minimal (40 %)	327.5	324.6	32.68
	June - Sep.	minimal (40 %)	327.5	324.6	32.68
South Europe	Mar. - May	minimal (40 %)	535.2	530.8	53.43
	June - Sep.	minimal (40 %)	431.3	427.7	43.05

Table 8.8-9781: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_highK_{oc} following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		265.3	135.4	1.23E+4
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	47.31	8.226	656.7
	June - Sep.	full canopy (60 %)	47.31	8.226	656.7
South Europe	Mar. - May	full canopy (60 %)	47.31	10.94	984.5
	June - Sep.	full canopy (60 %)	47.31	9.585	820.6
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	48.81	18.97	1820
	June - Sep.	full canopy (60 %)	48.81	18.97	1820
South Europe	Mar. - May	full canopy (60 %)	48.81	27.08	2800
	June - Sep.	full canopy (60 %)	48.81	23.02	2310

Table 8.8-9882: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_lowK_{oc} following multiple application of GWN 10616 to vines BBCH 79

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1890	1870	174.5
Step 2 - single application					
North Europe	Mar. - May	full canopy (60 %)	93.16	92.29	9.289
	June - Sep.	full canopy (60 %)	93.16	92.29	9.289
South Europe	Mar. - May	full canopy (60 %)	139.6	138.4	13.93
	June - Sep.	full canopy (60 %)	116.4	115.3	11.61
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (60 %)	258.3	255.9	25.76
	June - Sep.	full canopy (60 %)	258.3	255.9	25.76
South Europe	Mar. - May	full canopy (60 %)	396.7	393.3	39.59
	June - Sep.	full canopy (60 %)	327.5	324.6	32.68

Table 8.8-~~99~~83: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_highK_{oc} following multiple application of GWN 10616 to pome fruit with application rate 1500 g PA/ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		426.4	113.1	8220
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	172.1	22.4	1480
	June - Sep.	full canopy (65 %)	172.1	22.4	1480
South Europe	Mar. - May	full canopy (65 %)	172.1	24.8	1770
	June - Sep.	full canopy (65 %)	172.1	23.6	1630
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	165.7	33.6	2660
	June - Sep.	full canopy (65 %)	165.7	33.6	2660
South Europe	Mar. - May	full canopy (65 %)	165.7	38.4	3230
	June - Sep.	full canopy (65 %)	165.7	36.0	2950

Table 8.8-~~100~~84: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_lowK_{oc} following multiple application of GWN 10616 to pome fruit with application rate 1500 g PA/ha

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1510	1490	150.2
Step 2 - single application					
North Europe	Mar. - May	full canopy (65 %)	210.7	208.4	21.0
	June - Sep.	full canopy (65 %)	210.7	208.4	21.0
South Europe	Mar. - May	full canopy (65 %)	251.3	248.7	25.0
	June - Sep.	full canopy (65 %)	230.9	228.6	23.0
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (65 %)	377.9	373.9	37.6
	June - Sep.	full canopy (65 %)	377.9	373.9	37.6
South Europe	Mar. - May	full canopy (65 %)	458.9	454.3	45.7
	June - Sep.	full canopy (65 %)	418.3	414.1	41.68

Table 8.8-~~101~~85: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_highK_{oc} following multiple application of GWN 10616 to potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		143.5	105.8	10600
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	13.6	4.4	435.9
	June - Sep.	average (50 %)	13.6	4.4	435.9
South Europe	Mar. - May	average (50 %)	13.6	7.2	777.5
	June - Sep.	average (50 %)	13.6	5.8	606.6
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	13.28	12.2	1230
	June - Sep.	average (50 %)	13.28	12.2	1230
South Europe	Mar. - May	average (50 %)	23.5	22.3	2250
	June - Sep.	average (50 %)	18.4	17.3	1740

Table 8.8-~~102~~86: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_lowK_{oc} following multiple application of GWN 10616 potatoes BBCH 21

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1500	1480	149.4
Step 2 - single application					
North Europe	Mar. - May	average (50 %)	61.6	61.2	6.16
	June - Sep.	average (50 %)	61.6	61.2	6.16
South Europe	Mar. - May	average (50 %)	110.1	109.3	11.0
	June - Sep.	average (50 %)	85.9	85.2	8.6
Step 2 - multiple application					
North Europe	Mar. - May	average (50 %)	173.7	172.3	17.3
	June - Sep.	average (50 %)	173.7	172.3	17.3
South Europe	Mar. - May	average (50 %)	318.1	315.6	31.8
	June - Sep.	average (50 %)	245.9	243.9	24.6

Table 8.8-~~103~~87: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_highK_{oc} following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		143.5	105.9	10600
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	13.5	3.3	299.2
	June - Sep.	full canopy (70 %)	13.5	3.3	299.2
South Europe	Mar. - May	full canopy (70 %)	13.5	5.0	504.2
	June - Sep.	full canopy (70 %)	13.5	4.1	401.7
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	11.9	7.7	818.3
	June - Sep.	full canopy (70 %)	11.9	7.7	818.3
South Europe	Mar. - May	full canopy (70 %)	15.3	14.2	1430
	June - Sep.	full canopy (70 %)	12.3	11.2	1120

Table 8.8-~~104~~88: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for PI_lowK_{oc} following multiple application of GWN 10616 to potatoes BBCH 89

Scenario FOCUS	Waterbody	Crop cover	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw.twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---		1500	1480	149.4
Step 2 - single application					
North Europe	Mar. - May	full canopy (70 %)	42.4	42.0	4.2
	June - Sep.	full canopy (70 %)	42.4	42.0	4.2
South Europe	Mar. - May	full canopy (70 %)	71.4	70.8	7.1
	June - Sep.	full canopy (70 %)	56.9	56.4	5.7
Step 2 - multiple application					
North Europe	Mar. - May	full canopy (70 %)	116.0	114.9	11.6
	June - Sep.	full canopy (70 %)	116.0	114.9	11.6
South Europe	Mar. - May	full canopy (70 %)	202.6	200.1	20.2
	June - Sep.	full canopy (70 %)	159.3	157.9	15.9

No Step 3 calculations were performed for Phosphate ions.

No Step 4 calculations were performed for Phosphate ions.

$PEC_{sw/sed}$ of formulation

PEC_{sw} for the formulated product GWN-10616 were calculated based on spray drift only, using the FOCUS SWASH drift calculator. The maximum recommended rate to be applied is 1 x ~~4.275~~ 4.350 kg product/ha considering a product density of ~~1.425~~ 1.45 kg/L. Calculations were performed for Vines late application. Results are presented in the following table.

Table 8.8-~~10~~589: PEC_{sw} of the formulated product GWN-10616

Crop	Rate [g/h]	PEC_{sw} [µg/L] of GWN-10616		
		Ditch	Pond	Stream
Vines	~~4275~~ 4350	~~73.72~~ 75.01	~~2.62~~ 2.67	~~61.18~~ 62.25

8.9 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Review Comments:

The data on atmospheric degradation and behavior in air for zoxamide and potassium phosphonates / phosphonic acid provided by the Applicant are considered acceptable. No further evaluation is required.

Table 8.9-1 Summary of atmospheric degradation and behaviour for Zoxamide

Compound	Zoxamide
Direct photolysis in air	Not studied, no data necessary.
Quantum yield of direct phototransformation	(Φ) = 0.0225 (λ > 290 nm)
Photochemical oxidative degradation in air	DT_{50} (h): 7.5; derived by Atkinson calculation method, assuming a hydroxyl radical concentration of 1.5 x 10^6 OH/cm^3 and a 12 hour day. Rate constant for reaction with hydroxyl radicals: 17.1 x 10^{-12} cm^3/(molecule sec.)
Volatilisation	Vapour pressure (Pa): 1.3x10^{-5} Pa at 25°C Henry's Law Constant (Pa x m^3/mol): n.a. (not volatile) From plant surfaces: 5.1% AR after 24 hours. From soil: 3.9% AR after 24 hours.
Metabolites	No applicable.

The vapour pressure at 25°C of the active substance Zoxamide is 1.3 x 10^{-5} Pa. Thus, according to EVA 3rev.2h, the active substance Zoxamide is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Zoxamide due to volatilisation with subsequent deposition is not considered.

No data on the vapor pressure of Potassium phosphonates / Phosphonic acid were submitted or required. The product is produced as an aqueous solution. Neither the active, nor the technical substance is volatile, nor is there a chance of dust forming. Therefore, fate and behaviour in air is not relevant for this active substance or product.

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. (Doc. No.) Source (where different from company) GLP or GEP status (where relevant) Published or unpublished	Verte-brate study Y/N	Owner
KCP 9.1.3/01	Anonymous	2023	RAW DATA TO PECsoil FOR ZOXAMIDE AND ITS METABOLITES REL. TO THE dRR FOR THE CENTRAL ZONE FOR GWN-10616 PP272-00128/7-1 (782-003) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	XXXX
KCP 9.1.3/02	Anonymous	2023	RAW DATA TO PECsoil FOR PHOSPHONIC ACID REL. TO THE dRR FOR THE CENTRAL ZONE FOR GWN-10616 PP272-00128/7-2 (782-004) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	XXXX
KCP 9.2.4.1/01	Anonymous	2023	RAW DATA TO PECgw FOR ZOXAMIDE AND ITS METABOLITES REL. TO THE dRR FOR THE CENTRAL ZONE FOR GWN-10616 PP272-00128/7-3 (782-005) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	XXXX
KCP 9.2.4.1/02	Anonymous	2023	RAW DATA TO PECgw FOR PHOSPHONIC ACID REL. TO THE dRR FOR THE CENTRAL ZONE FOR GWN-10616 PP272-00128/7-4 (782-006) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	XXXX
KCP 9.2.4.1/03	Anonymous	2024	RAW DATA TO PECgw FOR ZOXAMIDE AND ITS METABOLITES REL. TO THE dRR FOR THE CENTRAL ZONE FOR GWN-10616 PP272-00128/7-27 (782-029) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	XXXX
KCP 9.2.5/01	Anonymous	2023	RAW DATA TO PECsw FOR ZOXAMIDE AND ITS METABOLITES REL. TO THE dRR FOR THE CENTRAL ZONE FOR GWN-10616 PP272-00128/7-5 (782-007) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	XXXX

Data point	Author(s)	Year	Title Company Report No. (Doc. No.) Source (where different from company) GLP or GEP status (where relevant) Published or unpublished	Verte-brate study Y/N	Owner
KCP 9.2.5/02	Anonymous	2023	RAW DATA TO PECsw FOR PHOSPHONIC ACID AND PHOSPHATE IONS REL. TO THE dRR FOR THE CENTRAL ZONE FOR GWN-10616 PP272-00128/7-6 (782-008) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	XXXX
KCP 9.2.5/03	Anonymous	2024	RAW DATA TO PECsw FOR ZOXAMIDE AND ITS METABOLITES REL. TO THE dRR FOR THE CENTRAL ZONE FOR GWN-10616 PP272-00128/7-28 (782-030) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	XXXX

na = not applicable / ni = not indicated / nr = not relevant

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

ZOXAMIDE

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
KCA 7.1.1.1	Burgener, A	1998	^{14}C-RH-117281: Rate of degradation and metabolism in four soils incubated under aerobic conditions Rohm and Haas, Report No. 34-98-45, September 17 1998, ER ref. no. 18.2 RCC Umweltchemie AG, Report No. 626196 GLP Not published	N	XXXX
KCA 7.1.1.1	Smalley, J, Reynolds, JL	1997	Aerobic soil metabolism of [^{14}C]-RH-117281 Fungicide Rohm and Haas, Report No. 34-96-07, June 26, 1997, ER ref. no. 6.13 XenoBiotic Laboratories Inc., Report No. RPT00256 GLP Not published	N	XXXX
KCA 7.1.1.2	Kim-Kang, H	1997	Anaerobic soil metabolism of [^{14}C]-RH-117281 Rohm and Haas, Report No. 34-97-43, April 9 1997, ER ref. no. 8.16 XenoBiotic Laboratories Inc., Report No. RPT00267 GLP	N	XXXX

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
			Not published		
KCA 7.1.1.2	Voelkel, W	1998	^{14}C-RH-117281: degradation in one soil incubated under anaerobic conditions Rohm and Haas, Report No. 34-98-46, September 3, 1998, ER ref. no. 4.5 RCC Umweltchemie AG, Report No. 626207 GLP Not published	N	XXXX
KCA 7.1.1.3	Reynolds, JL	1997	Soil photolysis of [^{14}C]-RH-117281 Rohm and Haas, Report No. 34-96-214, July 31, 1997, ER ref. no. 10.2 XenoBiotic Laboratories Inc., Report No. RPT00261 GLP Not published	N	XXXX
KCA 7.1.2.1.1	Callow, B. and Hilton, H.	2013	Determination of rates of decline for zoxamide and its metabolites in soil according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, UK, Report No. 0907598.UK0 EWC 0021 No GLP Not published	N	XXXX
KCA 7.1.2.1.1	Burgener, A	1998	^{14}C-RH-117281: Rate of degradation and metabolism in four soils incubated under aerobic conditions, Rohm and Haas, Report No. 34-98-45, September 17, 1998, ER ref. no. 18.2 RCC Umweltchemie AG, Report No. 626196 GLP Not published	N	XXXX
KCA 7.1.2.1.1	Smalley, J, Reynolds, JL	1997	Aerobic soil metabolism of [^{14}C]-RH-117281 Fungicide Rohm and Haas, Report No. 34-96-07, June 26, 1997, ER ref. no. 6.13 XenoBiotic Laboratories Inc., Report No. RPT00256 GLP Not published	N	XXXX
KCA 7.1.2.1.2	Callow, B. and Hilton, H.	2013	Determination of rates of decline for zoxamide and its metabolites in soil according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, UK, Report No. 0907598.UK0 EWC 0021 No GLP Not published	N	XXXX
KCA 7.1.2.1.2	Van den Bosch,	2013	Determination of the aerobic degradation rate of RH-141,455 in soil	N	XXXX

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
	M.M.H.		WIL Research Europe B.V., The Netherlands, Report No. 500850 GLP Not published		
KCA 7.1.2.1.3	Kim-Kang, H	1997	Anaerobic soil metabolism of [^{14}C]-RH-117281 Rohm and Haas, Report No. 34-97-43, April 9, 1997, ER ref. no. 8.16 XenoBiotic Laboratories Inc., Report No. RPT00267 GLP Not published	N	XXXX
KCA 7.1.2.1.3	Voelkel, W	1998	^{14}C-RH-117281: degradation in one soil incubated under anaerobic conditions Rohm and Haas, Report No. 34-98-46, September 3, 1998, ER ref. no. 4.5 RCC Umweltchemie AG, Report No. 626207 GLP Not published	N	XXXX
KCA 7.1.3.1.1	Shelby, DJ	1996	Adsorption and desorption of RH-117281 to soil Rohm and Haas Report No. 34-96-01, February 9, 1996, ER ref. no. 7.2 Ricerca Inc., Report No. 95-0224 GLP Not published	N	XXXX
KCA 7.1.3.1.2	Van den Bosch, M.M.H.	2013	Adsorption/desorption of RH-141,455 on three soils WIL Research Europe B.V., The Netherlands, Report No. 500851 GLP Not published	N	XXXX
KCA 7.1.3.1.2	Reynolds, J.L.	1998	Adsorption and desorption of ^{14}C-RH-24549 in three soils Rohm and Haas, Report No. 34-98-53, October 14, 1998, ER ref. no. 18.1 XenoBiotic Laboratories Inc., Report No. 706050 GLP Not published	N	XXXX
KCA 7.1.3.1.2	Voelkel, W.	1998	Adsorption/Desorption of RH-127450 on Three Soils Rohm and Haas, Report No. 34-98-54, December 15, 1998, ER ref. no. 25.4 RCC Ltd., Report No. 688116 GLP Not published	N	XXXX

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
KCA 7.1.3.1.2	Voelkel, W.	1998	Determination of the Adsorption Coefficient of ^{14}C-RH-163353 on Soil and its Octanol/Water Partition Coefficient Using High Performance Liquid Chromatography (HPLC) Rohm and Haas, Report No. 34-98-55, November 9, 1998, ER ref. no. 31.4 RCC Ltd., Report No. 689951 GLP Not published	N	XXXX
KCA 7.1.3.1.2	Voelkel, W.	2000	Adsorption/Desorption of RH-163,353 In Three Soils Rohm and Haas, Report No. 34-00-06, January 31, 2000, ER ref. no. 40.7 RCC Ltd., Report No. 733948 GLP Not published	N	XXXX
KCA 7.1.4.1.2	Voelkel, W.	1998	^{14}C-RH-117281: Leaching characteristics of aged residues in one soil Rohm and Haas, Report No. 34-98-48, September 15, 1998, ER ref. no. 4.4 RCC Umweltchemie AG, Report No. 636895 GLP Not published	N	XXXX
KCA 7.2.1.1	Reynolds, J.L.	1998	Hydrolysis of [^{14}C]-RH-117281 in Water at pH 4, 7, and 9 Rohm and Haas, Technical Report Number 34-98-39, September 29, 1998, ER ref. no. 15.2 XenoBiotic Laboratories Inc., Report No. RPT00251 GLP Not published	N	XXXX
KCA 7.2.1.1	Chong, B.P.	1998	RH-117281 Fungicide: Hydrolysis rates of relevant degradation products Rohm and Haas, Technical Report No. 34-98-26, September 30, 1998, ER ref. no. 30.16 GLP not relevant Not published	N	XXXX
KCA 7.2.1.2	Smalley, J. and Reynolds, J.L.	1998	Aqueous photolysis of [^{14}C]-RH-117281 Rohm and Haas, Report No. 34-96-215, May 12, 1998, ER ref. no. 12.5 XenoBiotic Laboratories Inc., Report No. RPT00259 GLP Not published	N	XXXX
KCA 7.2.2.1	Barnes, SP, Nave, V	1998	RH-117281 - Assessment of ready biodegradability: modified Sturm test Rohm and Haas, Report No. 98RC-1028, December 14, 1998, ER ref. no. 29.1 Huntingdon Life Sciences Limited, Report No. RAS 080/983376	N	XXXX

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
			GLP Not published		
KCA 7.2.2.2	Van den Bosch, M.M.H.	2014	Aerobic mineralisation of zoxamide in surface water WIL Research Europe B.V., The Netherlands, Report No. 503495 GLP Not published	N	XXXX
KCA 7.2.2.3	Callow, B. and Hilton, H.	2013	Determination of rates of decline for zoxamide and its metabolites, in sediment-water studies according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, UK, Report No. 0907598.UK0/EWC0020 No GLP Not published	N	XXXX
KCA 7.2.2.3	Morgenroth, U	1998	^{14}C-RH-117281: Degradation and metabolism in aquatic systems Rohm and Haas, Report No. 34-98-47, September 15, 1998, ER ref. no. 4.3 RCC Umweltchemie AG, Report No. 624510 GLP Not published	N	XXXX
KCA 7.3.2	Burgener, A	1998	Investigation of the volatilization of ^{14}C-RH-117281 from soil and dwarf runner bean Rohm and Haas Technical Report No. 34-98-132, August 24, 1998, ER ref. no. 14.2 RCC Ltd, Report No. 687295 GLP Not published	N	XXXX
KCP 9.1.1.1/01	Derz, K.	2020	AEROBIC DEGRADATION OF RH-24549 IN THREE SOILS MKC-004/5-30 (721-001) Fraunhofer-Institute for Molecular Biology and Applied Ecology (IME), Schmallenberg, Germany GLP, unpublished	N	XXXX
KCP 9.1.1.1/02	Klein, J. Mendel-Kreusel, R.	2020	RE-CALCULATION OF THE DEGRADATION OF RH-141455 AND RH-24549 IN SOIL BASED ON THE STUDY DATA OF DERZ K. (2020): AEROBIC DEGRADATION OF RH-24549 IN THREE SOILS GOW0720-1 (721-002) Mendel-Kreusel Consult, Eitorf, Germany Not GLP, unpublished	N	XXXX
KCP 9.1.1.1/03	Kercher, S.	2017	ENANTIOSELECTIVE DEGRADATION OF (R)-ZOXAMIDE AND (S)-ZOXAMIDE IN ONE	N	XXXX

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
			SOIL INCUBATED UNDER AEROBIC CONDITIONS (FINAL REPORT AMENDMENT NO. 1) AS520 (721-003) Rheinland-Pfalz AgroScience GmbH, Neustadt/Wstr., Germany GLP, unpublished		
KCP 9.2.5/03	Klein, J. Klein, M. Mendel-Kreusel, R.	2020	RESIDUE DISSIPATION OF ZOXAMIDE ON/IN SALAD PLANTS IN THE OPEN FIELD IN SOUTHERN EUROPE AND INDOOR GOW1020-1 (782-001) Mendel-Kreusel Consult, Eitorf, Germany Not GLP, unpublished	N	XXXX
KCP 9.2.5/04	Klein, J. Mendel-Kreusel, R.	2020	RESIDUE DISSIPATION OF ZOXAMIDE ON/IN PLANTS GOW1120-1 (782-002) Mendel-Kreusel Consult, Eitorf, Germany Not GLP, unpublished	N	XXXX
KCP 9.2.5/05	Appeltauer, A.	2020	DETERMINATION OF RESIDUES OF ZOXAMIDE ON/IN TYPICAL FEED ITEMS OF HERBIVOROUS BIRDS AND MAMMALS AFTER TWO APPLICATIONS OF ZOXIUM 240 SC ON SUGAR BEET AND WHEAT IN GERMANY 2017 S16-05375 (644-003) Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP, unpublished	N	XXXX
KCP 9.2.5/06	Appeltauer, A.	2020	DETERMINATION OF RESIDUES OF ZOXAMIDE ON/IN TYPICAL FEED ITEMS OF HERBIVOROUS BIRDS AND MAMMALS AFTER TWO APPLICATIONS OF THE TEST ITEM ON SUGAR BEET AND WHEAT IN THE NETHERLANDS IN 2019 S19-01450 (644-004) Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP, unpublished	N	XXXX
KCP 9.2.5/07	Appeltauer, A.	2020	DETERMINATION OF RESIDUES OF ZOXAMIDE ON/IN TYPICAL FEED ITEMS OF HERBIVOROUS BIRDS AND MAMMALS AFTER TWO APPLICATIONS OF ZOXIUM 240 SC ON SUGAR BEET AND WHEAT IN SOUTHERN EUROPE 2017 S16-05376 (644-005) Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP, unpublished	N	XXXX
KCP 9.2.5/08	Appeltauer, A.	2020	DETERMINATION OF RESIDUES OF ZOXAMIDE ON/IN TYPICAL FEED ITEMS OF HERBIVOROUS BIRDS AND MAMMALS AFTER TWO APPLICATIONS OF THE TEST ITEM	N	XXXX

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
			ON SUGAR BEET AND WHEAT IN ITALY IN 2020 S19-23773 (644-006) Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP, unpublished		
KCP 9.2.5/09	Luciani, P.	2013	DETERMINATION OF ZOXAMIDE AND DIMETHOMORPH RESIDUES AFTER TWO APPLICATIONS OF ZOXIUM 240 SC AND GWN-9963 ON LETTUCE, ROCKET SALAD AND ENDIVE UNDER FIELD CONDITIONS - ITALIAN TRIAL YEAR 2012 AGRI 013/12 GLP DEC (644-007) Agriparadigma S.R.L., Ravenna, Italy GLP, unpublished	N	XXXX
KCP 9.2.5/10	Luciani, P.	2013	DETERMINATION OF ZOXAMIDE AND DIMETHOMORPH RESIDUES AFTER TWO APPLICATIONS OF ZOXIUM 240 SC AND GWN-9963 ON LETTUCE AND ROCKET - ITALIAN TRIAL YEAR 2012 AGRI 014/12 GLP DEC (644-008) Agriparadigma S.R.L., Ravenna, Italy GLP, unpublished	N	XXXX

Potassium phosphonate

Data point	Author(s)	Year	Title Company Report No. (Doc. No.) Source (where different from company) GLP or GEP status (where relevant) Published or unpublished	Verte-brate study Y/N	Owner
KCA 7.1.1.1	Adams, F., Conrad, J.P.	1953	Transition of phosphite to phosphate in soils. Soil Science, 75, 361-371. Published	N	NA
KCA 7.2.1	Voelkel	1998	Na_2HPO_3 liquid solution. Degradation rate in three soils incubated under aerobic conditions report no. B30690 GLP: Yes Unpublished	N	ISK

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

- Boesten. J. (1997): Soil persistence models and EU registration (Doc. 7617/VI/96).
- FOCUS (2006) “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration” Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp
- EFSA (2014) European Food Safety Authority. Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 38 pp., doi:10.2903/j.efsa.2014.3662
- FOCUS (2000): FOCUS groundwater Scenarios in the EU review of active substance. Review of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202pp.
- European Commission (2000) Guidance Document on Persistence in Soil, Doc 9188/VI/97 rev. 8, 12.07.2000
- European Commission (2014) “Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU” Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp.
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- FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2.245pp.
- FOCUS (2007): Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.
- FOCUS (2008). Pesticides in Air: Considerations for Exposure Assessment. Report of the FOCUS Working Group on Pesticides in Air, EC Document

Reference SANCO/10553/2006 rev 2 June 2008. 327 pp

- FOCUS (2011): Generic guidance for FOCUS surface water Scenarios, Version 1.0, January 2011
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- FOCUS (2014) Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Version 1.1, December 2014
- FOCUS (2015): Generic guidance for FOCUS surface water Scenarios, Version 1.4, May 2015
- FOCUS (2021): Generic guidance for Tier 1 FOCUS Ground Water Assessments, Version 2.3, June 2021
- PPR Panel (2007): Opinion of the Scientific Panel on Plant protection products and their Residues on a request from EFSA on the Final Report of the FOCUS Air Working Group on Pesticides in Air: Consideration for exposure assessment. (SANCO/10553/2006 draft 1 (13 July 2006)).
- SANCO (2010) Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, SANCO/2010/13170 rev. 13, 14 July 2015
- SANCO (2021) Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev.11-final, 21 October 2021

Compound related references

- European Commission, 2017. Conclusion on the peer review of the pestice risk assessment of the active substance Zoxamide. EFSA Journal 2017;15(9):4980
- European Commission, 2018. Final renewal report for the active substance Zoxamide finalised in the Standing Committee on Plants, Animals, Food and Feed, SANTE/10052/2018 Rev 2
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- European Commission, 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance disodium phosphonate. EFSA Journal 2013;11(5):3213

The following tables are to be completed by MS

List of data submitted by the applicant and not 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

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 Study 1 – Aerobic degradation of RH24549

This active substance related study has already been provided to the RMS Latvia. Thus, the summary of the study is only presented for completeness' sake. The study is only indicated in the list of data submitted or referred to by the applicant and relied on.

Comments of zRMS:	The confirmatory-like studies were evaluated by the RMS-LV for zoxamide and its metabolites in an interzonal procedure. All details are to be found in the file: Zoxamide_confirmatory_like_data_Part_B5_B6_B8_B9_ XXXX _LV_2023, Part B – Section 8, available on CIRCABC. RMS-LV conclusion: The study is considered acceptable and the results can be used for risk assessment purposes.

Reference: **KCP 9.1.1.1/01**

Report: Derz, K., 2020: Aerobic degradation of RH-24549 in three soils
Gowan Crop Protection Ltd., UK
Fraunhofer IME, Germany, Report No. MKC-004/5-30, GLP, Not published

Guideline(s): OECD 307 (2002)

Deviations: Incubation of soil samples was carried out in a temperature-controlled room where the temperature was set to 20°C. During pre-test 1 the actual temperature in the incubation room was not documented so that it cannot be verified that the temperature was in the range of 20 ± 2°C. However, temperature was monitored throughout pre-tests 2-4 and the main test and was in the temperature range of 20 ± 2°C as given by the guideline.

GLP: Yes

Acceptability: Yes

The transformation of RH-24549 was investigated under aerobic conditions in the dark in three biologically active soils. The study intended to determine the degradation rates of RH-24549 (precursor of RH-141455) and RH-141455 (transformation product of RH-24549) as well as the formation fraction of RH-141455 developed from RH-24549. The incubation was performed using ^{14}C-labelled RH-24549 at an application rate of 0.24 mg/kg soil dry weight. Hence, radioanalytical methods were used in order to determine the amounts of radiolabelled RH-24549 as well as its transformation product RH-141455 and other radiolabelled molecules.

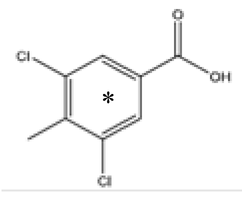
Materials and methods

A. Materials

1. Test material [phenyl-U-^{14}C]-RH-24549

Chemical name: 3,5-dichloro-4-methyl-benzoic acid

Chemical structure:



* label position

Description: white solid

Lot/batch: 6087SJR001-2

Purity: 99.4% (area, HPLC method)

Specific radioactivity: 5.47 MBq/mg

Expiry date: 08 March 2023 (date fixed by the testing facility)

2. Soils: Three top soils were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 2-2: Physico-chemical parameters of the soils

Soil	Sand [1] [%]	Silt [2] [%]	Clay [3] [%]	C_{org} [%]	pH [4]	Cation exchange capacity [mmol/kg]	WHC_{max}[5]
RefeSol 01-A (sandy loam)	74	20	6	0.96	5.7	4	293
RefeSol 02-A (silt loam)	6	78	16	1.06	6.8	58	416
RefeSol 05-G (loam)	33	47	20	2.10	4.9	72	666

[1] particle size: 50 µm - 2 mm
[2] particle size: 2 µm - 50 µm
[3] particle size: < 2 µm
[4] determined in 0.01 M CaCl2
[5] Maximum water holding capacity given in g H_2O/kg dry mass; the water holding capacity is also called field moisture capacity (= FMC)

The soils were sieved < 2 mm and their moisture content adjusted to about 45 % of their maximum water holding capacity (WHC_{max}). The soil samples were analysed for their actual microbial biomass during soil preparation as well as at the beginning, during and at the end of the incubation phase. During the incubation period, biomass was determined by the substrate induced respiration method in untreated samples and in samples treated with RH-24549 (nominal 12 µg/50 g soil dry mass). The results are expressed as biomass in mg microbial carbon per kg soil. They demonstrate an active microbial population throughout the incubation period.

Table A 2-3: Microbial biomass determined by means of substrate induced respiration method during the study (Mean values of two replicates)

Soil type	Soil sample	Biomass [mg C_{mic}/kg dry mass]		
		0 days	**16 days**	**End[1]**
RefeSol 01-A	Non-treated	133	82	104
	Treated *	-	77	104
RefeSol 02-A	Non-treated	205	187	217
	Treated *	-	195	210
RefeSol 05-G	Non-treated	211	239	178
	Treated *	-	228	210

* treated with test item
[1] Biomass determination at the end of incubation was carried out at 59 days (RefeSol 01-A), 42 days (RefeSol 02-A) and 80 days (RefeSol 05-G) after application.

B. Methods

1. Experimental conditions

Four pretests were carried out to gather information on the necessary time points for sampling and the appropriateness of the test system. After a first pretest at 20 ± 2°C in the dark using four different soils and a flow-through system, further pretests were carried out using the soil RefeSol 02-A to check test systems with different equipment in order to be able to establish a mass balance between 90 % and 110 % of the applied radioactivity (AR). On the basis of these pretests it was decided to use the flow-through test system equipped with screw fittings in the main test for all soil subsamples. Additional combustion of the outgoing gas flow did not improve the recovery of radioactivity in pretest 3, i.e. organic volatiles which were not trapped by ethylene glycol were negligible.

For the main experiment, portions of sieved soils (50 g dry weight) were pre-incubated in sterilised glas vessels for 18-19 days. The water content of the soil samples was adjusted to and kept at about 45 % WHC_{max}. The test item was solved in acetonitrile, the solvent evaporated to dryness and re-dissolved in sterile distilled water. The application solution was homogenised and applied at nominal amounts of 12 µg per sample (50 g dry mass) under sterile conditions. Incubation of subsamples was performed in a flow-through test system equipped with screw fittings, placed in a dark, temperature-controlled lab-room at 20 ± 2°C.

For sterile controls, 50 g soil samples (dry weight), were weighed into glass vessels, the vessels were sterilised twice at an interval of 3 days by autoclaving for 20 minutes at 121°C and 2 bar, and the water content of the sterilised soil samples was adjusted by addition of sterilised water under sterile conditions.

A constant stream of water saturated air was passed over the subsamples in order to maintain aerobic conditions during the experiments. The outgoing gas was bubbled by means of a vacuum pump through three absorption traps in sequence containing ethylene glycol and two traps of 1 M NaOH, in order to quantify volatile metabolites and to determine the rate of mineralisation. At every sampling date or every 7-10 days the absorption traps were removed and replaced by new ones.

2. Sampling

Replicate soil samples were taken to analyse [^{14}C]-labelled substance concentrations at the following time points after test item application:

- RefeSol 01-A: 0 d (immediately after application), 1 d, 2 d, 4 d, 8 d, 16 d, 23 d, 30 d and 60 d after application. Sterilised subsamples were taken after 0 d, 8 d and 60 d.
- RefeSol 02-A: 0 d (immediately after application), 1 d, 2 d, 4 d, 8 d, 16 d, 23 d, 30 d and 42 d after application. Sterilised subsamples were taken after 0 d, 8 d and 42 d.
- RefeSol 05-G: 0 d (immediately after application), 2 d, 4 d, 8 d, 15 d, 22 d, 36 d, 50 d and 80 d after application. Sterilised subsamples were taken after 0 d, 8 d and 80 d.

Description of the analytical procedure

Soil samples were extracted by acetonitrile: water: hydrochloric acid (70:30:0.5, v:v:v). Extracts were analysed for the test substance and possible degradation products by radio-TLC (quantitatively and qualitatively) and radio-HPLC (qualitatively).

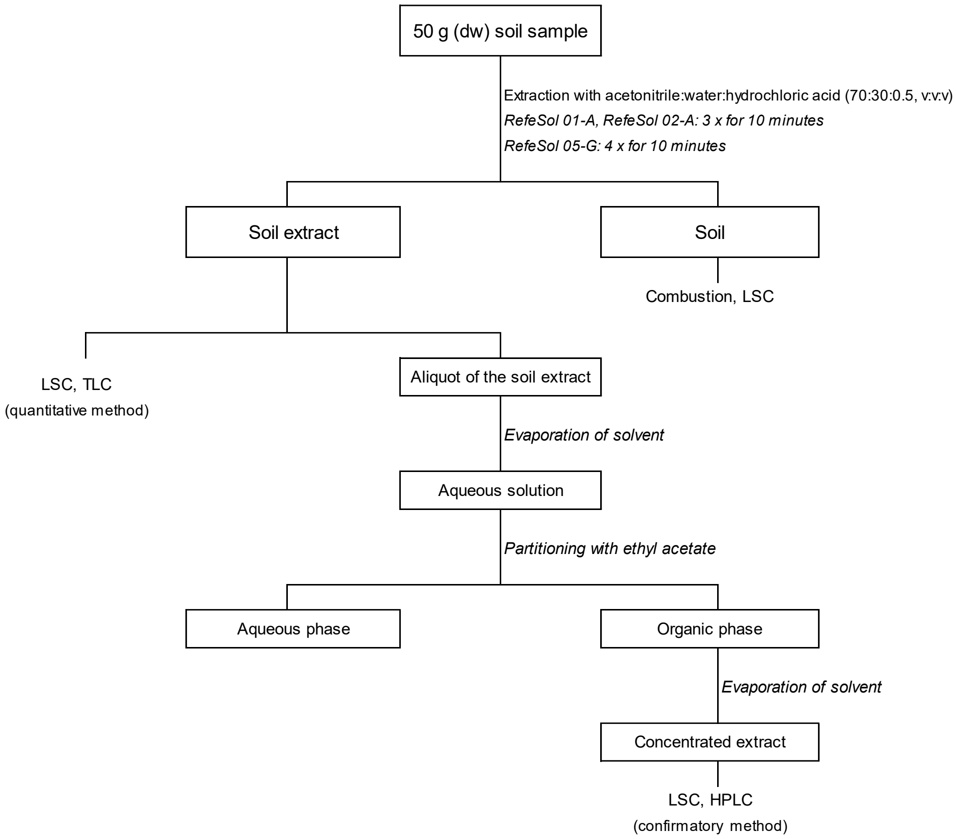


Figure A 1: Sample preparation scheme

Soil samples were extracted three times (RefeSol 01-A, RefeSol 02-A) or four times (RefeSol 05-G) with 50 mL acetonitrile:water:hydrochloric acid (70:30:0.5, v:v:v) for 10 minutes on a horizontal shaker. Soil and solvent phase were separated by centrifugation for 10 minutes at 2000 rpm, and afterwards, the extracts were combined. The total radioactivity in the combined extracts was determined by LSC. Aliquots were analysed by radio-HPLC and radio-TLC.

The remaining soil samples were air dried in a fume hood and ground to a uniform consistency and then five replicates (100 - 200 mg each) of each soil sample were combusted using an Oxidizer. The resulting $^{14}CO_2$ was trapped in Oxysolve C-400 and afterwards quantified by LSC. Each vial (volume: 20 ml) was measured 5 minutes in a Packard Tri-Carb scintillation counter. The efficiency of oxidation was determined by combustion of quality control standards.

Representative connection tubes and screw fittings between the sample vessels and the ethylene glycol traps were transferred into glass centrifuge tubes and were extracted on a horizontal shaker with 25 mL acetonitrile/water/hydrochloric acid (70:30:0.5, v:v:v) for 1 hours. Afterwards, the volumes of the extracts were determined and the extracts were analysed by LSC.

At each sampling time and every 7-10 days the absorption traps were sampled. Immediately after sampling the volume of each trapping solution was measured and total radioactivity in each solution was determined by LSC. The pH of the NaOH-absorption traps amounted always to pH 14.

Aliquots of extracts were analysed by radio-TLC without any further preparation step.

For radio-HPLC analysis, aliquots of the acetonitrile:water:hydrochloric acid (70:30:0.5., v:v:v) extracts were evaporated to the aqueous solution. The aqueous solution was transferred into a separation funnel and partitioned twice with 25 mL ethyl acetate by shaking vigorously for 1 minute. The ethyl acetate phases of the two partition steps were combined. 200 µL keeper solution (1% glycerine in acetone) was added to the ethyl acetate extract and the ethyl acetate was evaporated using a rotary evaporator. The residue was re-dissolved in methanol:water (1:1, v:v) and centrifuged for 5 minutes at 14000 rpm. The supernatant was transferred into an HPLC vial and was filled up to a defined volume. The resulting solution was homogenised thoroughly, and the total radioactivity was analysed by LSC before radio-HPLC analysis

Extraction efficiencies

In order to validate the extraction procedure, recovery experiments were performed in duplicate using both radiolabelled RH-24549 and RH-141455.

Regarding the soil extraction procedure for RH-24549, soil samples (50 g dry weight each, in duplicate) of RefeSol 01-A, RefeSol 02-A, RefeSol 04-A and RefeSol 05-G were applied with 65.64 kBq 14C-labelled RH-24549 corresponding to 12 µg/sample and 12 µg of non-labelled RH-141455. The soil samples were extracted as described above and the extracts were analysed by LSC. Applying this method, recovery of radioactivity in the soil extracts was 98.5 % (RefeSol 01-A), 94.8 % (RefeSol 02-A), 96.3 % (RefeSol 04-A) and 93.3 % (RefeSol 05-G) of the nominal radioactivity (mean values of two replicates).

Regarding the soil extraction procedure for RH-141455, soil samples (50 g dry weight each, in duplicate) of RefeSol 01-A, RefeSol 02-A, RefeSol 04-A and RefeSol 05-G were applied with 60.12 kBq 14C-labelled RH-141455 corresponding to 12 µg/sample and 12 µg of non-labelled RH-24549. The soil samples were extracted as described above and the extracts were analysed by LSC. Applying this method, recovery of radioactivity in the soil extracts was 101.3 % (RefeSol 01-A), 94.2% (RefeSol 02-A), 96.8 % (RefeSol 04-A) and 97.6 % (RefeSol 05-G) of the nominal radioactivity (mean values of two replicates).

Liquid scintillation counting (LSC)

After mixing an aliquot of the solution of interest with an aliquot of a suitable liquid scintillation cocktail (e.g. Ultima Gold LLT for aqueous samples and Ultima Gold for organic samples) LSC measurements were performed using a Hidex or Packard Tri-Carb liquid scintillation counter. Each sample was measured for 5 minutes in duplicate. Computer-constructed quench curves, derived from a commercially available series of sealed quench standards (from Packard), automatically convert cpm to dpm.

Radio-thin layer chromatography (radio-TLC)

TLC-plates:	MERCK precoated TLC-plates 20 x 20 cm, layer thickness 0.25 mm
Stationary phase:	Silica gel 60 F_{254} or RP-18 F_{254S}
Mobile phase:	Ethyl acetate: 2-propanol: formic acid (85:13:2; v:v:v) for quantification. For further solvent systems used (e.g. for pretests or polar metabolites), please refer to the study report.
Application volume:	1 – 140 µl (depending on sample radioactivity)
Type:	1 dimensionary TLC (1D-TLC)
Distance from start to solvent front:	about 150 mm
Typical R_f values:	R_f ~ 0.70 (RH-24549), R_f ~ 0.61 (RH-141455), R_f ~ 0,67 (RH-141452)
Imaging:	GE Healthcare Typhoon FLA 7000, Amersham Typhoon
LOQ:	between 1.25 µg/kg and 1.84 µg/kg (non-concentrated extract)
LOD:	half of the specified amounts of the limit of quantification

Radio-high performance liquid chromatography (radio-HPLC)

<u>Instrument</u>

HPLC pump:	LPG 3400 SD, Thermo Fisher Scientific
Autosampler:	WPS-3000 SL, Thermo Fisher Scientific

UV detector:	Diode array Ultimate 3000, Thermo Fisher Scientific
Radioactivity detector:	Ramona Star, Raytest
Chromatographic data system:	Pyramid Valuestation with Chromeleon Vers. 6.80 and Chromeleon 7, Thermo Fisher Scientific

Chromatographic conditions

Stationary phase:	PerfectSil Target ODS-3 C18, 5 µm from MZ Analysentechnik
Column dimension:	4.6 x 250 mm
Injection volume:	50-250 µL
UV detection:	3D Field, λ = 200 – 600 nm
Wavelength:	230 nm, 249 nm (UV-VIS 1,2)
Temperature:	Ambient
Flow rate:	1.0 mL/min
Mobile phase:	A: water with 0.1% formic acid B: acetonitrile with 0.1% formic acid

Time [min]	% A	% B
0	98	2
20	0	100
21	98	2
25	98	2

Retention time(s):	~ 18.0 min (UV-detection, RH-24549) 7.7 minutes (UV-detection, RH-141455) 11.3 minutes (UV-detection, RH-141452)

Results and discussions

A. Mass balance

The total radioactivity balance and the distribution of radioactivity in every subsample were established at each sampling day. The overall recoveries of soils RefeSol 01-A and RefeSol 02-A ranged between 90 and 110 % of initially applied radioactivity for all samples except for the sampling on 23 days (RefeSol 01-A, 87.6 % AR) and the sampling on 8, 16 and 42 days (RefeSol 02-A, 78.5 % AR – 88.4 % AR). The overall recoveries of soil RefeSol 05-A ranged between 92.0 % and 100.0 % of applied radioactivity during the first 15 days of incubation. Thereafter, recoveries in the range of 65.7 % AR and 85.4 % AR were determined. In sterile samples of all soils the overall recovery was always > 90 % AR. On the basis of extensive pretesting, it is assumed that the formed $^{14}CO_2$ could not be trapped completely during incubation and/or sampling/sample preparation. Formation of organic volatiles was excluded due to the results of pretests. Negligible radioactivity (< 0.1 % AR) was found adsorbed to the vessel connection's and fitting's inner surfaces.

B. Volatilisation

Volatile radioactivity increased continuously from 0.4 % AR – 1.5 % AR at 2 days up to a maximum of 55.7 % AR (RefeSol 01-A) at the end of incubation. In the other soils maximum values of 48.8 % AR (RefeSol 02-A) and 45.5 % AR (RefeSol 05-G) were detected in the sodium hydroxide traps at 30 days or 50 days of incubation (mean values of two replicates). Since the volatile radioactivity was mainly found in sodium hydroxide traps (trapping of $^{14}CO_2$), the results show that mineralisation of the test item occurred during the aerobic incubation of RH-24549, demonstrating complete degradation of the test item.

C. Transformation of parent compound (RH-24549)

The amount of radioactivity extracted from soil by acetonitrile:water:hydrochloric acid (70:30:0.5, v:v:v) decreased in all soils from 92.1 % – 96.3 % AR at the beginning of incubation continuously to 7.5 % – 11.6 % AR at the end of incubation. The amount of non-extractable radioactivity (NER) increased from 2.2 % - 8.0 % AR at day 0 to maximum values of 23.0 % (RefeSol 05-G) – 36.9 % AR (RefeSol 02-A) after 23 days (RefeSol 02-A) – 36 days (RefeSol 05-G) of incubation. Afterwards, the non-extractable radioactivity decreased slightly until the end of incubation time to values between 22.4 % (RefeSol 05-G) and 31.4 % AR (RefeSol 02-A).

The parent compound RH-24549 in the soil extracts decreased from maximum levels between 92.1 % - 94.1 % AR immediately after application to amounts in the range of 1.8 % (RefeSol 02-A) - 8.4 % AR (RefeSol 05-G) until the end of incubation. The concentration of the transformation product RH-141455 increased to maximum values of 4.7 % AR (RefeSol 02-A), 6.9 % AR (RefeSol 01-A) and 13.0 % AR (RefeSol 05-G) at an incubation time between 8 to 16 days. Amounts of RH-141455 decreased thereafter to non-detectable values at the end of incubation. The soil metabolite RH-141452 did not appear at any relevant amount.

In addition to RH-141455, polar compounds remaining at the start area of the TLC-plate (start activity) demonstrate the extensive degradation of the parent compound to polar transformation products. However, start activity fraction is considered to be a sum of polar compounds and exceeded (at least) two times 5 % AR in soil extracts of RefeSol 01-A and RefeSol 05-G. However, when using an alternative TLC solvent system for the more polar compounds, this fraction can be separated into 3-5 individual peaks never exceeding 3 % AR. Further minor transformation products were detected in soil extracts of all soils but never exceeded 10 % AR or two times 5 % AR.

Table A 2-4: Composition of the radioactivity recovered in the acetonitrile/water/ HCl soil extracts by radio-TLC following application of RH-24549 to 3 soils

Mean values of two replicates; values given in % of applied radioactivity (% AR)

Days after application	**% Applied Radioactivity**								
	0	**1**	**2**	**4**	**8**	**16**	**23**	**30**	**60**
Soil RefeSol 01-A									
RH-24549	94.1	94.0	88.9	85.0	67.5	26.1	10.8	5.8	3.3
RH-141455	--	0.9	2.0	4.3	6.1	6.9	5.6	3.1	--
Start activity	2.2	0.9	3.6	1.0	2.7	6.0	6.7	7.4	5.2
Unassigned Rf 0.36	--	--	--	--	--	0.5	1.6	0.7	0.9
Unassigned Rf 0.57	--	--	--	--	--	0.4	--	--	--
Microbial biomass (µg c/g soil)	133	--	--	--	--	--	--	--	--
Soil RefeSol 02-A									
Days after application	**0**	**1**	**2**	**4**	**8**	**16**	**23**	**30**	**42**
RH-24549	92.8	88.5	87.3	80.7	52.8	8.6	2.5	2.0	1.8
RH-141455	--	1.4	2.5	3.7	4.7	1.6	1.0	-	0.1
Start activity	1.8	2.4	0.4	2.2	4.6	5.4	4.4	4.8	4.7
Unassigned Rf 0.36	--	--	--	--	--	0.2	0.6	0.4	0.3
Unassigned Rf 0.57	--	--	--	--	--	0.7	--	0.4	0.6
Microbial biomass (µg c/g soil)	205	--	--	--	--	--	--	--	--
Soil RefeSol 05-G									
Days after application	**0**	**2**	**4**	**8**	**15**	**22**	**36**	**50**	**80**

Days after application	% Applied Radioactivity								
	0	1	2	4	8	16	23	30	60
RH-24549	92.1	80.0	70.7	53.8	45.2	35.5	11.5	4.7	8.4
RH-141455	--	4.8	7.4	13.0	9.0	6.3	3.1	0.5	--
Start activity		3.8	4.8	4.8	5.2	6.2	6.9	6.4	3.2
Unassigned Rf 0.48	--	--	--	--	--	--	--	0.7	--
Microbial biomass (µg C/g soil)	211	--	--	--	--	--	--	--	--

D. Calculation of DT_{50}/DT_{90} values and formation fractions

Based on the achieved experimental data, rate constants and DT_{50}/DT_{90} values of RH-24549 and of its degradation product RH-141455 in aerobic soil were calculated with the computer software CAKE version 3.3 running on R version 3.0.0. The kinetic models considered for the analysis of the RH-24549 degradation values were SFO (Single First Order), DFOP (Double First Order in Parallel), HS (Hockey Stick), and FOMC (First Order Multi Compartment).

Table A 2-5: Results of CAKE calculations for the RH-24549

Soil	Kinetics	chi²	DT_{50} (days)	DT_{90} (days)
RefeSol 01-A	SFO	9.96	9.36	31.1
	DFOP	11.2	9.36	31.1
	HS	**2.22**	**11.0^**	**24.6^**
	FOMC	10.5	7.67	25.5
RefeSol 02-A	SFO	13.2	6.99	23.2
	DFOP	14.9	6.99	23.2
	HS	**1.8**	**8.6^**	**15.9^**
	FOMC	14.0	4.85	16.1
RefeSol 05-G	**SFO**	**5.98**	**13.8^**	**45.9^**
	DFOP	6.89	13.8	45.9
	HS	6.14	13.0	47.4
	FOMC	6.38	12.5	41.5
RefeSol 05-G extended	SFO	7.42	14.0	46.7
	DFOP	7.94	13.5	50.9
	HS	7.47	12.9	49.6
	FOMC	7.65	13.3	50.8
Geometric mean			**10.9**	

^used to calculate the mean

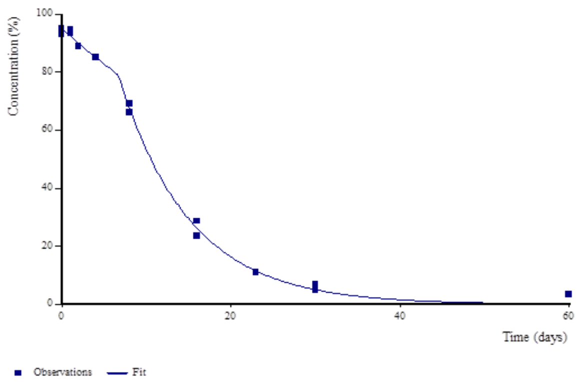
For RefeSol 05-G two CAKE calculations were carried out: one calculation including all sampling dates (0 days – 80 days, “extended”) and one calculation including all sampling dates except 80 days (0 days – 50 days). The reason was the difference in the distribution of radioactivity found in the extracts of both replicates 80 days after application. However, RH-24549 and RH-141455 reached already a sufficient degradation to 3.2 % - 6.2 % and 0.4 % - 0.7 % AR, respectively, 50 days after incubation. SFO gave the best fit for both data sets, but the analysis without the 80 days sampling values resulted in lower chi² value. As a result, the values in bold characters with the best fits were finally used to calculate a geometric mean DT_{50} of 10.9 days (n=3) for RH-24549.

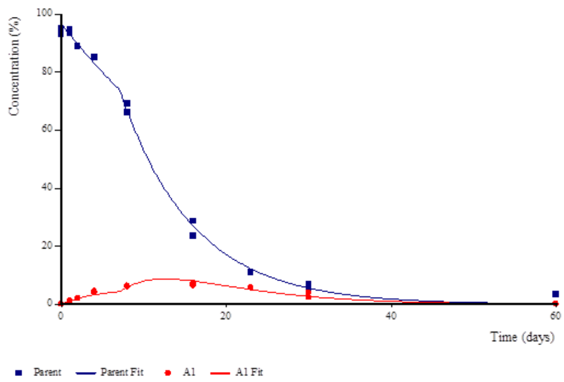
The residues of the transformation product RH-141455 were calculated including its formation fractions. The analysis for the metabolite RH-141455 was based on the best fit kinetics for the parent compound, for the metabolite always SFO degradation was considered.

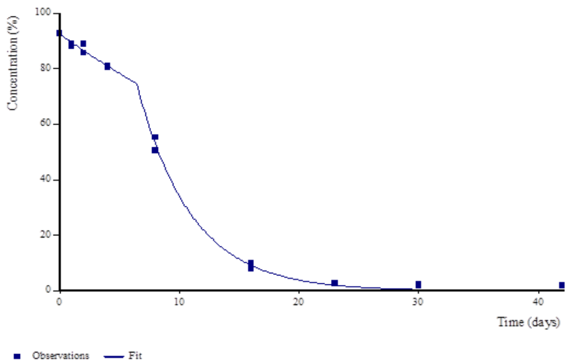
Table A 2-6: Results of CAKE calculations for the metabolite RH-141455

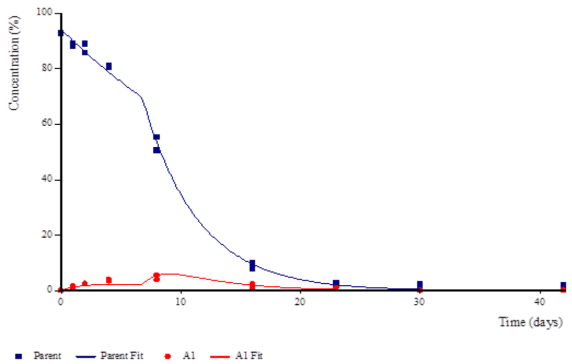
Soil	Kinetics	chi²	Formation fraction (-)	DT_{50} (days)	DT_{90} (days)
RefeSol 01-A	HS-SFO	13.2	0.3336	4.02	13.4
RefeSol 02-A	HS-SFO	29.1	0.3988	1.12	3.72
RefeSol 05-G	SFO-SFO	14.8	0.7822	3.22	10.7
Arithm. mean (n=3)			**0.505**		
Geometric mean (n=3)				**2.4**	

For RH-141455 a geometric mean DT_{50} of 2.4 days and an arithmetic mean formation fraction of 0.505 (n=3) were calculated.

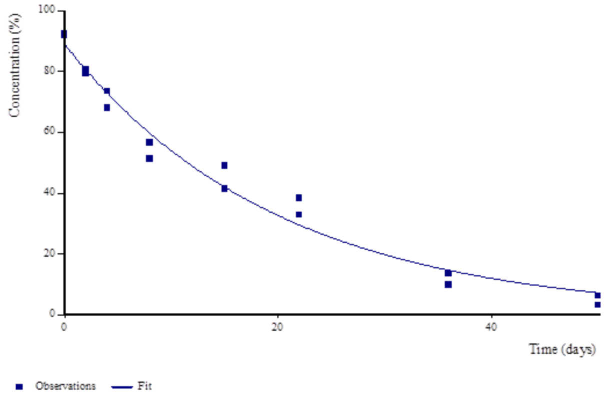
<table>
<tr><th>RH-245489</th><th>RH-141455</th></tr>
<tr><td>The figures show the fitted model together with the experimental residues.</td><td>The figures show the fitted model for RH-24549 and RH-141455 together with the experimental residues. The fit for RH-141455 was always based on SFO-Kinetics.</td></tr>
<tr><td>


Observations vs. experimental residues for RH-24549 in the soil RefeSol 01 A (Hockey Stick)</td><td>


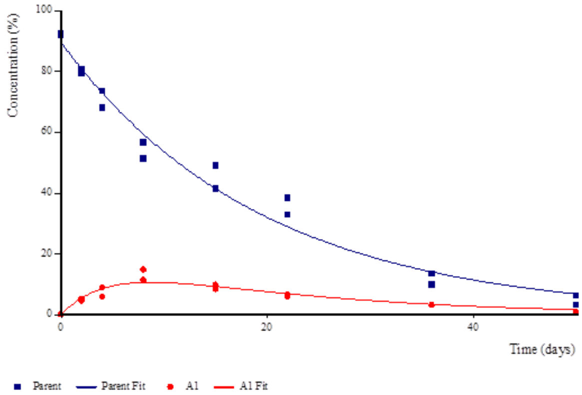
Observations vs. experimental residues for RH-24549 and RH-141455 in the soil RefeSol 01 A (RH-24549: Hockey Stick)</td></tr>
<tr><td>


Observations vs. experimental residues for RH-24549 in the soil RefeSol 02 A (Hockey Stick)</td><td>


Observations vs. experimental residues for RH-24549 and RH-141455 in the soil RefeSol 02 A (RH-24549: Hockey Stick)</td></tr>
</table>



Observations vs. experimental residues for RH-24549 in the soil RefeSol 05 G (Single First Order)



Observations vs. experimental residues for RH-24549 and RH-141455 in the soil RefeSol 05 G (RH-24549: Single First Order)

Conclusion

Additional in The transformation of [^{14}C]-RH-24549 was investigated under aerobic conditions in the dark in three biologically active soils. The study intended to investigate in depth the degradation behaviour of RH-24549 (precursor of RH-141455) and RH-141455 (transformation product of RH-24549) and to determine formation fractions for RH-141455 developed from RH-24549.

Based on best fit assumptions, a geometric mean DT_{50} of 10.9 days (n=3) was derived for RH-24549. For RH-141455 a geometric mean DT_{50} of 2.4 days and an arithmetic mean formation fraction of 0.505 (n=3) were calculated.

A 2.2 Study 2 – Soil degradation parameter of RH-141455 and RH-24549

This active substance related study has already been provided to the RMS Latvia. Thus, the summary of the study is only presented for completeness' sake. The study is only indicated in the list of data submitted or referred to by the applicant and relied on.

Comments of zRMS:	The confirmatory-like studies were evaluated by the RMS-LV for zoxamide and its metabolites in an interzonal procedure. All details are to be found in the file: Zoxamide_ confirmatory_ like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC. RMS-LV conclusion: The study is considered overall acceptable, except for formation fraction (ff) value of 0.5 for metabo-lite RH-141455 in Mechthildshausen soil (see Table A 2-9). RMS agrees with the Applicant that from the study of Burgener (1998) with the parent compound zoxamide the ff from RH-24549 was calcu-lated at 0.5, however due to request by EFSA it was set to a default value of 1 for kinetic refitting of RH-141455 to obtain shorter DT50 value – 88.5 days (instead of 195.2 days) which would be more in line with DT50 values (1.12 to 31.7 days) from the metabolite dosed studies. Given the above, we believe that the correct ff value for the metabolite RH-141455 in Mechthildshau-sen soil is 1 and the correct arithmetic mean ff value is 0.629.

Reference:	**KCP 9.1.1.1/02**
Report	Klein, J., Mendel-Kreusel, R., 2020: Re-calculation of the degradation of RH-141455 and RH-24549 in soil based on the study data of Derz K. (2020): Aerobic degradation of RH-24549 in three soils Gowan Crop Protection Ltd., UK Mendel-Kreusel Consult, Germany, Report No. GOW0720-1, No GLP, Not published
Guideline(s):	FOCUS (2000)
Deviations:	No
GLP:	No
Acceptability:	Yes

Materials and methods

The soil degradation data of the zoxamide metabolites RH-141455 and RH-24549 from the study of Derz K. (2020): Aerobic degradation of RH-24549 in three soils, Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Schmallenberg, Germany, Study number: MKC-004/5-30, were normalised to standard reference conditions with regard to soil moisture (pF2) and compared to the values available in the EFSA Peer Review Conclusion (2017) for zoxamide. The values determined at 20°C were normalised according to the recommendations of the FOCUS Groundwater Scenarios Workgroup (FOCUS 2000). The following equation was used for the calculation:

$$DegT50(pF2) = DegT50\ (exp) \left(\frac{Moisture(\exp)}{Moisture\ (pF2)}\right)^{0.7}$$

$DegT_{50}$(exp):	exp. DegT50 (d)
$DegT_{50}$(pF2):	normalised half-life at pF 2 (d)
Moisture (exp):	experimental gravimetric soil moisture (g/g)
Moisture (pF2):	gravimetric soil moisture at pF 2 (g/g)

Results and discussions

In the following tables the normalised soil degradation data for RH-24549 and RH-141455 are depicted.

Table A 2-7: Normalised soil degradation values (20°C, pF2) of RH-24549

Soil type	Gravimetric soil moisture at FC (%)^	Experimental MWHC (%)	45% of MWHC (%)°	Correction factor	DT_{50} experimental (d)	DT_{50} at pF2 (d)
sandy loam	19	29.3	13.185	0.7743	11	**8.52**
silt loam	26	41.6	18.72	0.7946	8.6	**6.83**
loam	25	66.6	29.97	1.000*	13.8	**13.8**

° experimental conditions ^according to FOCUS (2000) * no correction since soil moisture was above pF2

Table A 2-8: Normalised soil degradation values (20°C, pF2) of RH-141455

Soil type	Gravimetric soil moisture at FC (%)^	Experimental MWHC (%)	45% of MWHC (%)°	Correction factor	DT_{50} experimental (d)	DT_{50} at pF2 (d)
sandy loam	19	29.3	13.185	0.7743	4.02	**3.11**
silt loam	26	41.6	18.72	0.7946	1.12	**0.89**
loam	25	66.6	29.97	1.000*	3.22	**3.22**

° experimental conditions ^according to FOCUS (2000) * no correction since soil moisture was above pF2

Normalised $DegT_{50}$ values (20°C, pF2) for RH-24549 were found in the range of 6.83 to 13.8 days. For RH-141455 the respective normalised $DegT_{50}$ values were in the range of 0.89 to 3.22 days.

Considering the evaluated soil degradation values of EFSA (2017) and the normalised $DegT_{50}$ values (20°C, pF2) of the new study of Derz (2020), overall geometric mean $DegT_{50}$ values for RH-24549 and RH-141455 were calculated at 6.84 and 7.48 days (n=7 each) for RH-24549 and RH-141455, respectively. The following tables summarise the available aerobic degradation rates for RH-24549 and RH-141455 from the EFSA Peer Review Conclusion (2017) including the new normalised data based on Derz (220).

Table A 2-9: Summary of aerobic degradation rates for RH-24549 - laboratory studies

RH-24549, laboratory studies, aerobic conditions										
Soil name or location	**Soil type**	**pH**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C & pF2**	**Chi^2 (%)**	**Kinetic model**	**Evaluaed on EU level y/n/ Reference**
Bordeaux, France	Loam	7.4	20	50	6.32	21	5.94	23.2	SFO-SFO	y (EFSA, 2017)
St. Margherita, Italy	clay loam	8.1	20	50	8.45	28.1	7.01	24.2	SFO-SFO	
Mechthildshausen, Germany	sandy loam	7.4	20	50	5.78	19.2	5.72[1]	30.7	SFO-SFO	
			20	100 (FC)	3.07	10.2	3.07	16	SFO-SFO	
Ohio, USA	loamy sand	6.9	25	75 (FC)	6.13	20.4	6.83	16.1	SFO-SFO	
RefeSol 01-A	sandy loam	5.7	20	45	11	24.6	8.52	2.22	HS	n (Derz, 2020)
RefeSol 02-A	silt loam	6.8	20	45	8.6	15.9	6.83	1.8	HS	
RefeSol 05-G	Loam	4.9	20	45	13.8	45.9	13.8	5.98	SFO	
						Geometric mean (n=7)	**6.84**			n
						pH dependency:	**y**			y (EFSA, 2017)

[1] according to EFSA (2017), for the calculation of the geometric mean value only the value for the German sandy loam at 20°C and 100% FC (no normalisation necessary) is considered

In aerobic soils the zoxamide metabolite RH-141455 develops from its precursor RH-24549. From the soil degradation study of Burgener (1998) with the parent compound zoxamide a formation fraction (ff) of 0.5 for RH-141455 developed from RH-24549 was determined (please refer to Volume 3 Part B. 8 of the final RAR for zoxamide, 2017). The study of Derz (2020) with [^{14}C]-RH-24549 as test item investigated further the degradation behaviour of RH-24549 and RH-141455 and the formation fraction of RH-141455. As a result, an overall arithmetic mean formation fraction of 0.504 (n=4) was found for the transformation of RH-24549 to RH-141455.

Table A 2-10: Results of CAKE calculations for the metabolite RH-141455

RH-141455, laboratory studies, aerobic conditions											
Soil name or location	**Soil type**	**pH**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C & pF2**	**Chi[2] (%)**	**Kinetic model**	**FF**	**Evaluated on EU level y/n/ Reference**
Mechthildshausen, Germany	sandy loam	7.4	20	50	88.5	294	87.62[1]	18.2	SFO-SFO	0.50 *	y (EFSA, 2017)
Speyer 2.2	loamy sand	5.5	20	40	12.0	40.0	12.00	6.95	SFO[2]	--	
Speyer 2.3	sandy loam	6.8	20	40	11.1	36.9	9.54	5.77	SFO[2]	--	
Speyer 6S	Clay	7.1	20	40	31.7	105.3	14.72	6.8	SFO[2]	--	
RefeSol 01-A	sandy loam	5.7	20	45	4.02	13.4	3.11	13.2	HS-SFO[3]	0.3336	n
RefeSol 02-A	silt loam	6.8	20	45	1.12	3.72	0.89	29.1	HS-SFO[3]	0.3988	
RefeSol 05-G	Loam	4.9	20	45	3.22	10.7	3.22	14.8	SFO-SFO[3]	0.7822	
						geometric mean (n=7)	**7.48**				n
						arithmetic mean (n=4)				**0.504**	
						pH-dependency:	n				y (EFSA, 2017)

* From the study of Burgener 1998 with the parent compound zoxamide the ff from RH-24549 was calculated at 0.5, but set to a default value of 1 by EFSA (2017)
[1] calculated from a study with the parent compound zoxamide; length of DT_{50} mainly due to low detections
[2] study conducted with RH-141455
[3] study conducted with RH-24549 as precursor of RH-141455

The half-lives for the soil metabolite RH-24549 available in the EFSA Conclusion (2017) are slightly lower than in the study of Derz (2020), but comparable.

The DT_{50} values for the soil metabolite RH-141455 available in the EFSA Conclusion (2017) are shorter compared to the Derz (2020) values.
The values for RH-141455 in the soil Mechthildshausen were derived from the soil metabolism and degradation study of Burgener (1998), and have been re-evaluated according to FOCUS (2006)[1] by Callow & Hilton (2013; report no. 0907598.UK0 EWC 0021). In this study the parent compound zoxamide has been applied at a rate of 150 g a.s./ha. Only single soil samples were analysed instead of duplicate samples. The metabolite RH-141455 appeared at generally very low detections. Therefore, only for the Mechthildshausen soil (performed at 50% MWHC and 20°C) an acceptable fit could be obtained for RH-141455 with a chi[2] % error >15%, but $P<0.05$ and an acceptable visual fit (see RAR Zoxamide 2017, Vol. 3, B.8). However, the goodness of fit and the resulting (long) $DegT_{50}$ value for this metabolite were markedly affected by its low residue values especially at the final time-points of the Burgener (1998) study.

[1] FOCUS (2006): Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005 version 2.0, 434 pp.

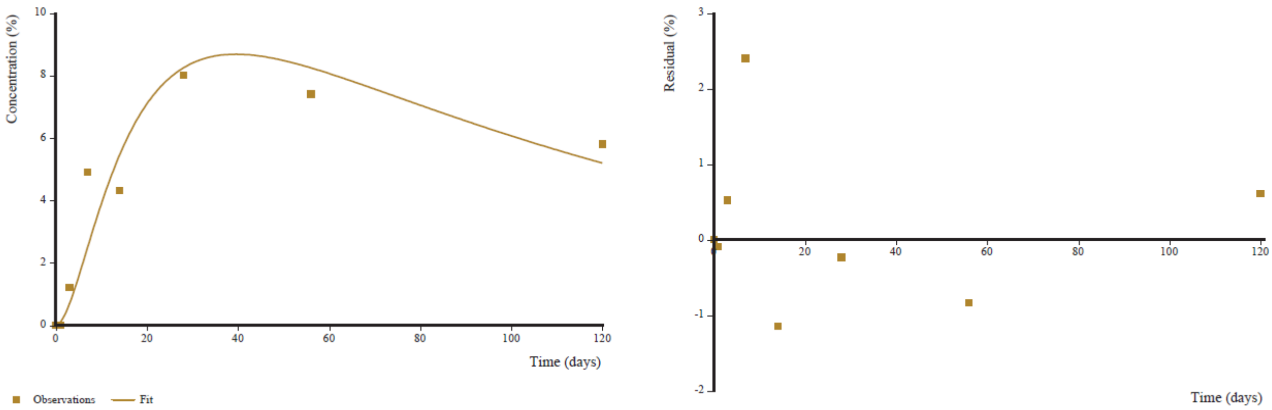


Figure A 2: Plot of the decline and the residuals of RH-141455 from the sandy loam Mechthildshausen derived at 20°C and 50% MWHC; SFO-SFO kinetics (see results for the study of Burgener 1998 in the RAR Zoxamide 2017, Vol. 3, B.8)

The additional soil degradation values for RH-141455 presented by EFSA (2017) were derived from an OECD 307 soil degradation study of Van den Bosch (2013; report no. 500850; see RAR 2017). In this study only single soil samples were analysed instead of duplicate samples and the microbial biomass had only been detected at study start but not at the end of soil incubation. The DT_{50} and DT_{90} values were calculated according to the FOCUS (2006, 2011[2]). They amounted to 12.0 days (SFO, DT_{90} of 40.0 days) for Speyer 2.2, 11.1 days for Speyer 2.3 (SFO, DT_{90} of 36.9 days) and 31.7 days for Speyer 6S (SFO, DT_{90} of 105.3 days). The related $DegT_{50}$ at standard reference conditions (pF2, 20°C) range from 9.54-14.72 days. This is longer compared to studies of Derz (2020) with $DegT_{50}$ values of 0.89-3.22 days. However, in the study of Van den Bosch (2013) the metabolite RH-141455 itself has been applied to the soil at an application rate of 0.2 mg/kg soil dry weight (150 g/ha), assuming a 100% formation from parent. In contrast, in the study of Derz (2020) the pre-cursor of RH-141455, the soil metabolite RH-24549, has been applied at a comparable application rate of 0.24 mg/kg soil dry weight. Therefore, in the study of Derz (2020) only the portion of RH-141455 formed from RH-24549 can further degrade. This portion amounts – under the more realistic degradation conditions of Derz (2020) - to maximum values of 7.3 % AR for RefeSol 01-A (see Table 6), 5.5 % AR for RefeSol 02-A (see Table 7) and 14.7 % AR for RefeSol 05G (see Table 8 in Klein & Mendel-Kreusel, 2020; report no. GOW0720-1).

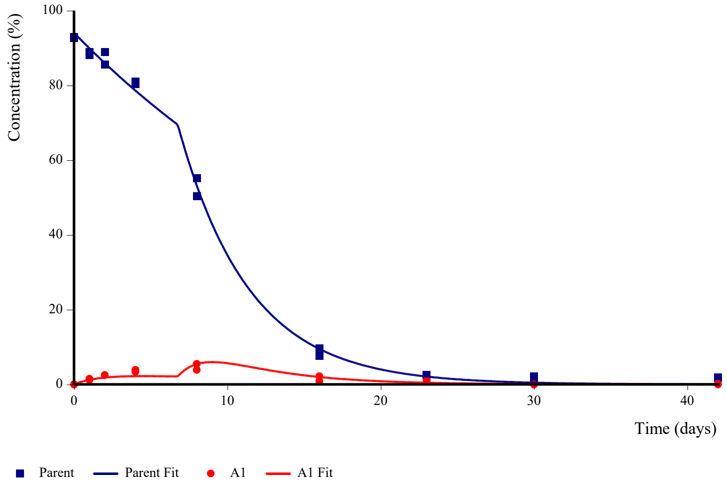
From modelling point of view, two different models are used for the kinetic evaluation of the degradation results of Derz (2020, report no. MKC-004/5-30) and Van den Bosch (2013, report no. 500850; see RAR 2017). For the Speyer soils (Van den Bosch 2013) RH-141455 was used directly and modelled as parent. For the RefeSol soils (Derz 2020) the study was conducted with RH-24549 as precursor of RH-141455 and thus a model with parent (RH-24549 as pre-cursor) and metabolite (RH-141455 as its transformation product) is used. The methods for evaluating the goodness of fit of parent and metabolite recommended by FOCUS (2014[3]) are the same: visual assessment and chi^2 statistics. For both the parent and the metabolite the chi^2 statistics is calculated separately.

Ideally, the chi^2 error for the metabolite should be below 15% (FOCUS 2014). However, this value is not an absolute cut-off criterion (FOCUS 2014). As an example, from the study by Derz (2020) the highest chi^2 error for RefeSol 02-A is considered in the following.

The best fit is obtained for this soil using the Hockey Stick (HS) kinetic for the pre-cursor (RH-24549) and Single First Order (SFO) for the metabolite (RH-141455). Visually the model fits the experimental data. The chi^2 error of parent is smaller than 3 %.

[2] FOCUS (2011): Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration, version 1.0, November 2011

[3] FOCUS (2014): Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration, version 1.1, December 2014



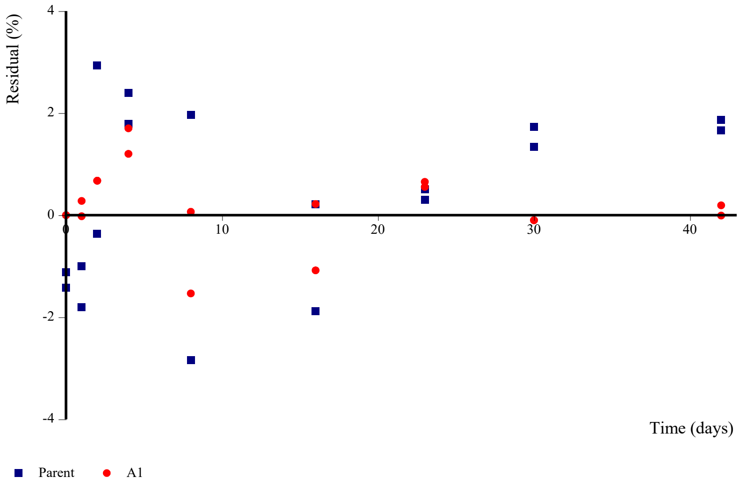


Figure A 3: **Plot of the decline and the residuals of RH-24549 and RH-141455 from the silt loam RefeSol-02 A, using HS kinetics for RH-24549 and SFO for RH-141455 (see Derz 2020)**

The residual plot shows a random distribution of residuals. The maximal deviation of model and experimental data of the metabolite is smaller than 2% (red dots). No systematic error is apparent during the formation, maximum or decline of the metabolite.

An additional goodness of fit criterion is the t-test. For a good statistical correspondence, the probability value shall be smaller than 0.05 (FOCUS 2014). For all rate constants, the probability is much smaller. Thus, the values of the rate constants and the resulting DT_{50} values are statistically reliable.

The relatively high chi² value for the transformation product RH-141455 (29.1 %) is caused by the low residue values of the metabolite (< 5.5 % AR). However, the fit still represents a reasonable description of its formation and degradation behaviour.

For RefeSol 01-A and RefeSol 05-G the chi² error for the metabolite is below 15%. The selected kinetics therefore describe reasonably the formation and degradation behaviour of the metabolite RH-141455 in the study of Derz (2020).

Conclusion

In aerobic soils the zoxamide metabolite RH-141455 develops from its precursor RH-24549.

Based on the study of Derz (2020), normalised $DegT_{50}$ values (20°C, pF2) for RH-24549 were found in the range of 6.83 to 14 days. For RH-141455 the respective normalised $DegT_{50}$ values were in the range of 0.89 to 3.22 days.

Considering the evaluated soil degradation values of EFSA (2017) and the normalised $DegT_{50}$ values (20°C, pF2) of the new study of Derz (2020), overall geometric mean $DegT_{50}$ values for RH-24549 and RH-141455 were calculated at 6.84 and 7.48 days (n=7 each) for RH-24549 and RH-141455, respectively.

From the soil degradation study of Burgener (1998) with the parent compound zoxamide a formation fraction (ff) of 0.5 for RH-141455 developed from RH-24549 was determined (please refer to Volume 3 Part B. 8 of the final RAR for zoxamide, 2017). The study of Derz (2020) with [^{14}C]-RH-24549 as test item investigated further the degradation behaviour of RH-24549 and RH-141455 and the formation fraction of RH-141455. As a result, an overall arithmetic mean formation fraction of 0.504 (n=4) was found for the transformation of RH-24549 to RH-141455.

A 2.3 Study 3 – Enantioselective degradation of Zoxamide in soil

The enantioselective degradation of (R)- and (S)-zoxamide in one soil incubated under aerobic conditions in the dark has been investigated by Kercher (2017). This study has been completed after the peer review of zoxamide data during AIR and considered in the EC Renewal Report (SANTE/10052/2018 rev. 2, dated 23 March 2018) on the following point mentioned in the EFSA Peer Review Conclusion (2017) for zoxamide:

The human health and environmental risk assessment consequent to potential changes in the isomer composition for zoxamide and metabolites RH-127450, RH-163353, [RH-150721 human health only] could not be finalised (see Sections 2, 3, 4 and 5).

For all of the substances assessed as racemic mixtures (zoxamide, RH-127450, RH-163353 and RH-150721), the chiral carbon is chemically stable, therefore interconversion is highly unlikely. Moreover, the available metabolism and degradation data do not show any preferential metabolism of one isomer over another one in either mammals, plants or the environment. ***A soil degradation study completed after the peer review showed no difference in rate of degradation of the isomers of neither zoxamide nor the major soil metabolite 127450.*** *Even making the worst-case assumption (all toxicity residues in one isomer and residues in crops comprised of only this isomer), dietary exposure would still be less than 8.2% the ADI.*

This active substance related study has already been provided to the RMS Latvia. Thus, the summary of the study is only presented for completeness' sake. The study is only indicated in the list of data submitted or referred to by the applicant and relied on.

Comments of zRMS:	The confirmatory-like studies were evaluated by the RMS-LV for zoxamide and its metabolites in an interzonal procedure. All details are to be found in the file: Zoxamide_ confirmatory_ like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC. RMS-LV conclusion: The study is considered acceptable

Reference:	**KCP 9.1.1.1/03**
Report	Kercher, S., 2017: Enantioselective degradation of (R)-zoxamide and (S)-zoxamide in one soil incubated under aerobic conditions Gowan Crop Protection Ltd., UK RLP AgroScience, Germany, Report No. AS520, GLP, Not published
Guideline(s):	OECD 307 (2002) SANCO/825/00 rev. 6 (2000) SANCO/3029/99 rev. 4 (2000)
Deviations:	The temperature in the incubation chamber should be held at 20±2 °C throughout the study, but it decreased to below 18 °C (min 17.7 °C) on 1 occasion for a time period <1 day. The average temperature remained at 20.2±0.1 °C. This deviation is regarded to not alter the results of the study.
GLP:	Yes
Acceptability:	Yes

Zoxamide is a racemate consisting of an (R)- and (S)-enantiomer at a 1:1 ratio. The objective of this study was to determine the enantioselective degradation of zoxamide and its metabolites under aerobic conditions in one soil at 20 °C in the dark. Following an incubation of the soil with non-radiolabelled test item at an application rate of 120 µg per 100 g dry soil, the concentrations of the isomers of zoxamide and its degradation products in soil were followed over a period of 29 days (i.e. when DT_{90} for zoxamide was reached).

The study was performed with non-radiolabelled test item and analysed by enantioselective liquid chromatography coupled with a tandem mass spectrometer detector. The analytical method was validated according to SANCO/825/00 rev. 6 (2000) and SANCO/3029/99 rev. 4 (2000). However, mass balances (including volatiles and unextractables) were not determined.

Materials and methods

A. Materials

1. Test material Zoxamide tech

Chemical name: (RS)-3,5-Dichloro-N-(3-chloro-1-ethyl-1-methylacetonyl)-p-toluamide

Description: beige solid

Lot/batch: 2015083101

Purity: 96.9 % (w/w)

Specific radioactivity: --

Expiry date: August 2017

Zoxamide tech. was used as test and reference item. In addition, possible degradation products of zoxamide served as reference items.

2. Soils: One top soil was chosen (20 cm, no chemical treatments last 3 years) to represent arable farming conditions in respect of soil texture and pH.

Table A 2-11: Physico-chemical parameters of the soil

Soil	Sand [1] [%]	Silt [2] [%]	Clay [3] [%]	C_{org} [%]	pH [4]	Cation exchange capacity [mmol/kg]	WHC_{max} [5]
Mußbach, Germany (loam)	46	38.1	15.9	1.5	7.6	120	31.53

[1] particle size: 50 µm - 2 mm
[2] particle size: 2 µm - 50 µm
[3] particle size: < 2 µm
[4] determined in 0.01 M CaCl2
[5] Maximum water holding capacity at pF 2.0

The soil was freshly sampled from the field and stored until use in the cooling chamber at ca. +4 °C for 10 days. It was regularly moistured. Storage and pre-incubation time together did not exceed three months. The soils were sieved < 2 mm and their moisture content adjusted to pF 2.5 (19.78 g H_2O/100 g dry soil). The microbial biomass was determined at the start and at the end of the incubation period - two replicates each (except day 0) for the control, solvent control and test item treated group. The results demonstrate an active microbial population throughout the incubation period.

Table A 2-12: Microbial biomass determined by means of SIR-method described by Anderson and Domsch[4]

Soil type	Soil sample	Biomass [mg C_{mic}/kg dry mass]	
		0 days	29 days (end)
Mußbach, Germany (loam)	Non-treated	36	35, 34
	Solvent control	-	35, 36
	Treated*	-	37, 33

* treated with test item and solvent

B. Methods

1. Experimental conditions

The test system consisted of gas tight 300 mL Erlenmeyer flasks closed with a quartz wool stopper to ensure free exchange with the atmosphere. For the experiment, portions of sieved soils (100 g dry weight) were pre-incubated for 4 days.

After attest item application, the homogeneity and concentration of the test item in the application solution was verified. For this, the application solution was diluted stepwise: first 1/100, second 1/100, and third 1/10 with acetonitrile/water 1/1 (v/v) and measured by LC-MS/MS.

The vessels were incubated under aerobic conditions in a climatic cabinet at 20.2 ± 0.1 °C in the dark. Soil moisture was kept at pF 2.5 (19.78 g H_2O/100 g dry soil; values from older batch) throughout the study period.

Following an incubation of the soil with non-radiolabelled test item at an application rate of 120 µg per 100 g dry soil (this corresponds to 900 g a.s./ha distributed in a 5 cm soil layer with a density 1.5 g/cm^3), the concentrations of the isomers of zoxamide and its degradation products in soil were followed over a period of 29 days (i.e. when DT_{90} for zoxamide was reached).

2. Sampling

After 0, 2, 4, 7, 14, 21 and 29 days of incubation duplicate samples were taken for analysis.

3. Description of the analytical procedure

The study was performed with non-radiolabelled test item and analysed by enantioselective liquid chromatography coupled with a tandem mass spectrometer detector. The analytical method was validated according to SANCO/825/00 rev. 6 (2000) and SANCO/3029/99 rev. 4 (2000). However, mass balances (including volatiles and unextractables) were not determined.

At each sampling interval, two replicates per soil were extracted. In order to check losses during the work up, one sample was freshly fortified at the expected concentration with zoxamide and processed concurrently to the treated samples.

Entire soil samples were extracted with 100 mL acetonitrile/water (100:2; v/v). The flasks were shaken for 30 minutes, the samples were centrifuged for 5 minutes at 2000 rpm, and the supernatants removed. The volumes were adjusted to 100 mL with water in volumetric flasks. Two aliquots per sample were taken, diluted with acetonitrile/water (1:1, v/v) with a factor of 100 and measured by LC-MS/MS. Each soil sample was extracted twice.

[4] J. P. E. Anderson, K. H. Domsch, A Physiological Method for the Quantitative Measurement of Microbial Biomass in Soils, Soil Biol. Chem. 10, 215-221, 1978

For detailed information on the analytical method validation, please refer to Part B, Section 5.

Results and discussions

A. Mass balance and volatilisation

Mass balances (including volatiles and unextractables) were not determined.

B. Transformation of parent compound (zoxamide)

The concentration of zoxamide in the application solution was determined at 3.18 µg/L. Compared to the applied amount of 127.12 µg/100g soil, this is 5.9% above the target amount.

Table A 2-13: Amount of applied test item zoxamide to 100 g dry soil

Enantiomer	**Test Item applied [µg]**
1-(RS)-zoxamide	63.72
2-(RS)-zoxamide	63.40
Sum (RS)-zoxamide	127.12

During the course of the study, the samples were processed immediately after sampling. Initial extraction procedures were completed within a single working day. Sample extracts were stored frozen at ca -18°C. Initial LC-MS/MS profiles of the extracts were obtained within 8 days of the sample generation. The analysis of RH-163353 was performed 38 days after application (due to a delayed shipment of the analytical standard). The fortified recovery samples processed and stored under the same conditions confirmed the stability of zoxamide in the sample extracts. Zoxamide and its metabolites were analysed by enantioselective LC-MS/MS with an LOQ of 0.002 mg/kg for zoxamide, RH-127450 and RH-163353. Since the reference standards were racemates, the assignment to (R)- or (S)-enantiomer was not possible. Therefore, the separated enantiomers were labelled by their retention times as 1-(RS) and 2-(RS)-enantiomers. The enantioselective separation of the metabolite RH-163353 could not be achieved with the used method and the concentration was calculated as sum of the enantiomers for this metabolite.

Table A 2-14: Analytes recovered in the acetonitrile/water (100:2; v/v) soil extracts by enantioselective LC-MS/MS after application of (RS)-zoxamide to 1 soil

Mean values of two replicates; values given in % of applied test item

Days after application	**% Applied Radioactivity**						
	0	**2**	**4**	**7**	**14**	**21**	**29**
Soil Mußbach, Germany							
1-(RS)-zoxamide	46.2	42.6	25.8	13.9	7.1	2.9	2.3
2-(RS)-zoxamide	45.8	42.1	28.9	15.6	7.0	3.3	2.5
1-(RS)-RH-127450	n.d.	4.3	4.8	6.7	2.6	0.7	0.6
2-(RS)-RH-127450	n.d.	3.7	4.7	5.3	3.3	1.0	0.8
(RS)-RH-163353	n.d.	1.7	2.8	3.4	2.8	1.1	0.4
Microbial biomass (µg C/g soil)	36	--	--	--	--	--	33-35

C. Calculation of DT_{50}/DT_{90} values and formation fractions

Based on the achieved experimental data, rate constants and DT_{50}/DT_{90} values for zoxamide and its soil metabolites were calculated with the computer software CAKE version 3.2. The kinetic models considered for the analysis were SFO (Single First Order) and FOMC (First Order Multi Compartment).

Table A 2-15: Results of CAKE calculations for zoxamide and its metabolites

Substance	Kinetics	chi²	DT_{50} (days)	DT_{90} (days)	CI (95%) (k)
1-(RS)-zoxamide	SFO	11.9	4.7	15.7	0.092 – 0.202
	FOMC	12.9	3.9	13.0	*
2-(RS)-zoxamide	SFO	9.9	5.2	17.2	0.091 – 0.177
	FOMC	10.7	4.3	14.3	*
1-(RS)-RH-127450 **	SFO	6.0	5.0	16.5	0.085 – 0.194
	FOMC	7.4	4.9	16.9	*
2-(RS)-RH-127450 **	SFO	10.8	7.5	25.1	0.020 – 0.164
	FOMC	13.5	6.9	22.9	*
(RS)-RH-163353 **	SFO	16.3	9.6	31.8	-0.023 – 0.168
	FOMC	20.4	8.0	26.7	*

* Confidence intervals contain 0
** For calculation of DT50/DT90 the highest amount (DAT7) was set to DAT0

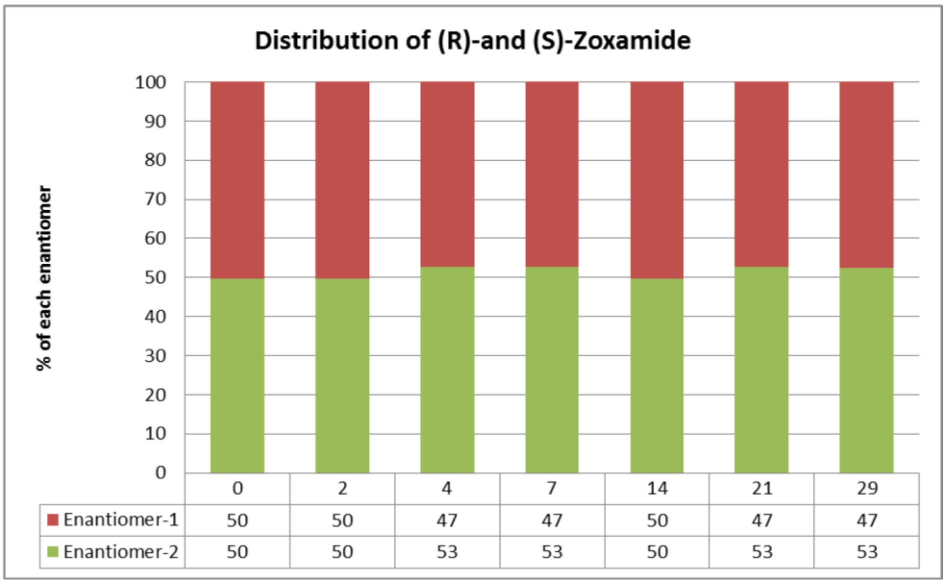


Figure A 4: Distribution of (R)- and (S)-Zoxamide over all sampling intervals

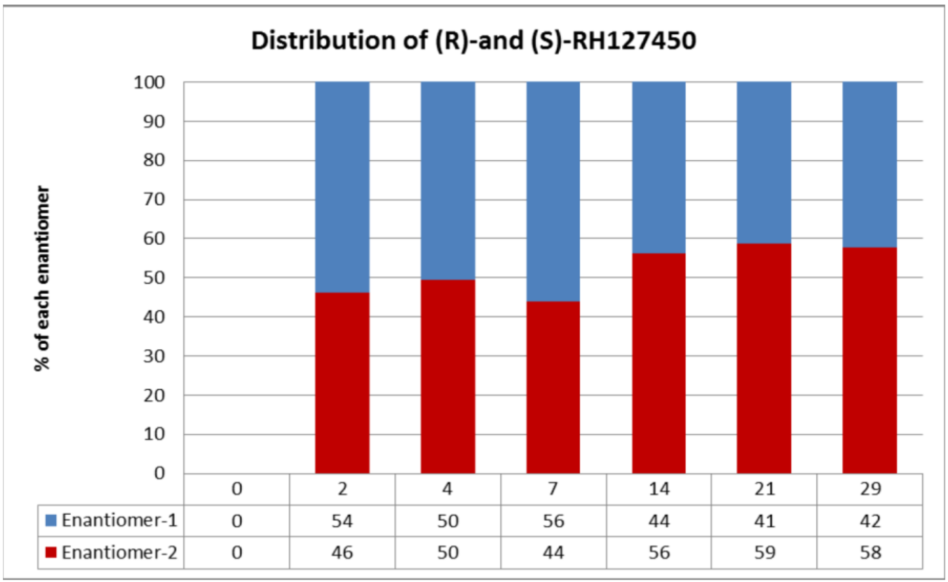
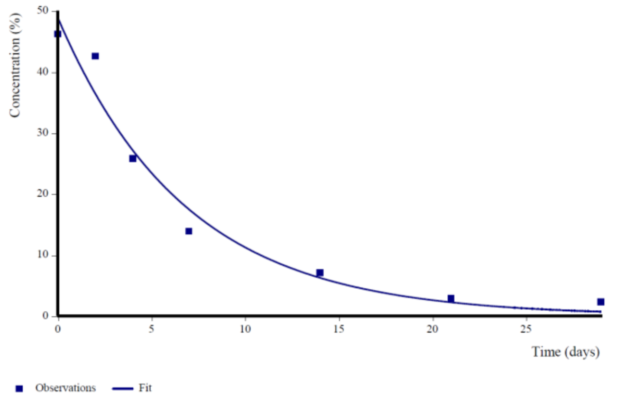
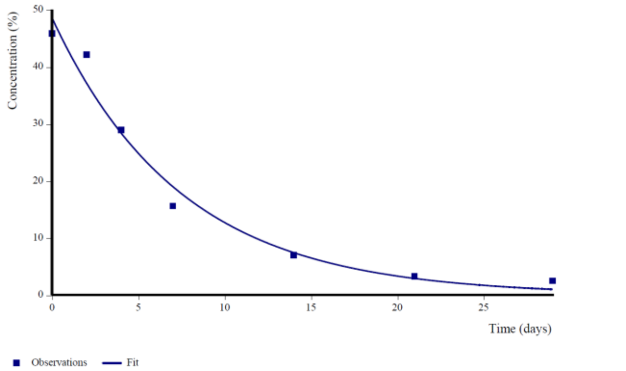
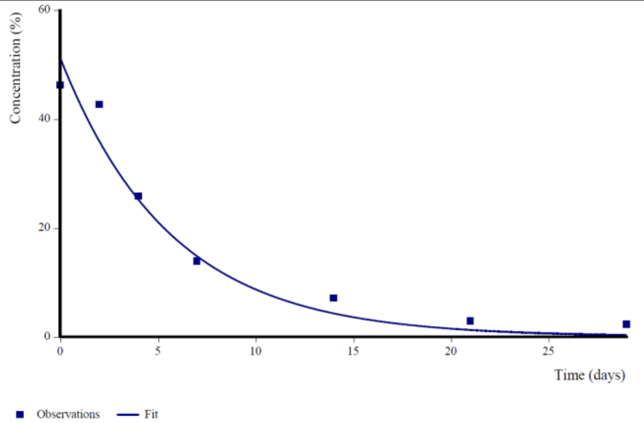
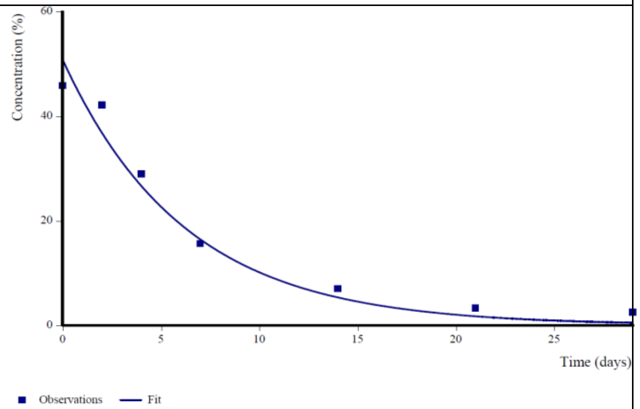
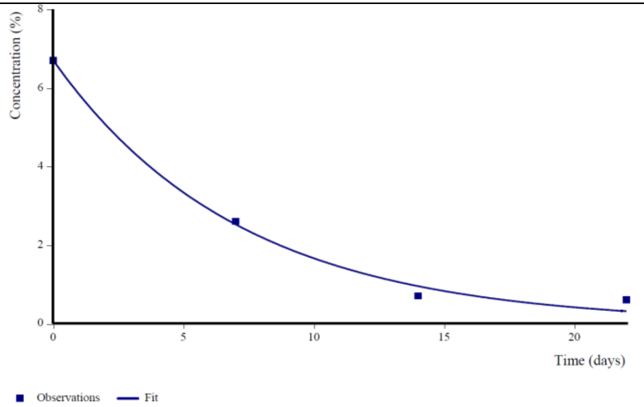


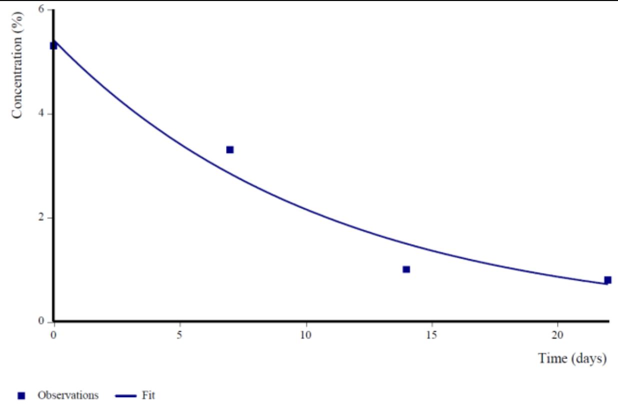
Figure A 5: Distribution of (R)- and (S)-RH-127450 over-all sampling intervals

The following figures show the fitted model (for Single First Order (SFO) and First Order Multi Compartment (FOMC) kinetics) together with the experimental residues.

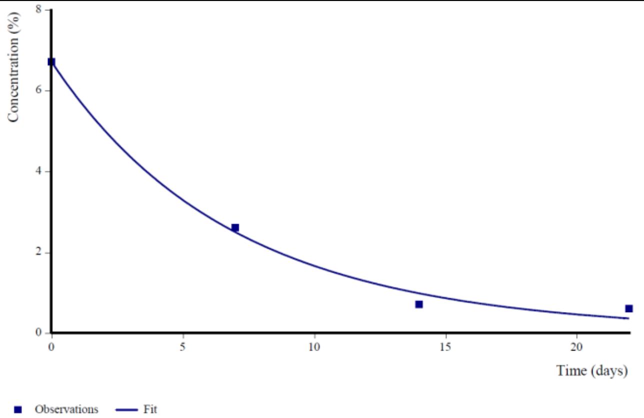
 Observations vs. experimental residues for 1-(RS)-zoxamide in the soil Mußbach (SFO)	 Observations vs. experimental residues for 2-(RS)-zoxamide in the soil Mußbach (SFO)
 Observations vs. experimental residues for 1-(RS)-zoxamide in the soil Mußbach (FOMC)	 Observations vs. experimental residues for 2-(RS)-zoxamide in the soil Mußbach (FOMC)
1-(RS)-RH-127450	2-(RS)-RH-127450



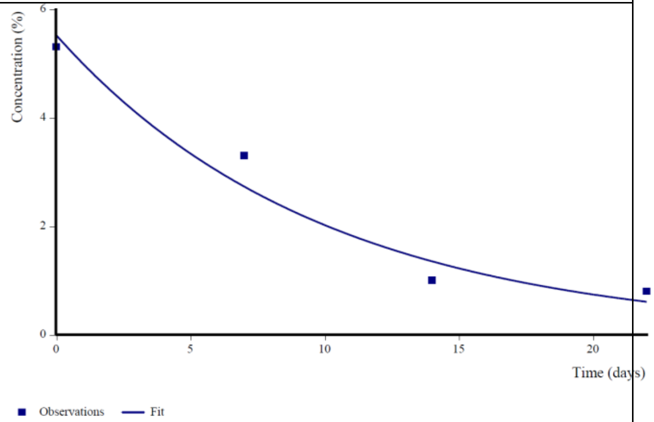
Observations vs. experimental residues for 1-(RS)-RH-127450 in the soil Mußbach (SFO)



Observations vs. experimental residues for 2-(RS)-RH-127450 in the soil Mußbach (SFO)



Observations vs. experimental residues for 1-(RS)-RH-127450 in the soil Mußbach (FOMC)



Observations vs. experimental residues for 2-(RS)-RH-127450 in the soil Mußbach (FOMC)

Conclusion

The enantioselective degradation of zoxamide and its metabolites RH-127450 and RH-163353 were evaluated in a typical arable soil under aerobic conditions at 20 °C in the dark. The enantiomers of zoxamide rapidly degraded with similar rates in soil under aerobic conditions with calculated SFO DT_{50} values of 4.7 - 5.2 days. The enantiomers of RH-127450 degraded also rapidly in soil under aerobic conditions with similar calculated SFO DT_{50} values of 5.0 - 7.5 days. No separation of the RH-163353 enantiomers was achieved. RH-163353 degraded rapidly with a calculated SFO DT_{50} of 9.6 days.

A 2.4 Study 4 – Residue dissipation of Zoxamide on/in plants

Substance specific DT_{50} values for residues dissipation of zoxamide were taken into account for refined PEC_{sw} calculations. These values were obtained for salad plants in residues decline trials of Luciani (2012) in reports no. AGRI 013/12 GLP DEC and AGRI 014/12 GLP DEC summarised in Part B Section 7. The residue data were kinetically re-evaluated by Klein et al. (2020; report no. GOW1020-1), the results of the kinetic evaluation are summarised in the following.

This active substance related study has already been provided to the RMS Latvia. Thus, the summary of the study is only presented for completeness' sake. The study is only indicated in the list of data submitted or referred to by the applicant and relied on.

Comments of zRMS:	The confirmatory-like studies were evaluated by the RMS-LV for zoxamide and its metabolites in an interzonal procedure. All details are to be found in the file: Zoxamide_ confirmatory_ like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC. RMS-LV conclusion: The kinetic re-evaluation of residue data was performed according to FOCUS (2014), therefore the RMS believes that the study is acceptable and the results of the kinetic evaluation can be used for risk assessment purposes.

Reference:	**KCP 9.2.5/03 (Doc. No. 782-001)**
Report	Klein, J., Klein, M., Mendel-Kreusel, R., 2020: Residue dissipation of zoxamide on/in salad plants in the open field in Southern Europe and indoor Gowan Crop Protection Ltd., UK Mendel-Kreusel Consult, Germany, Report No. GOW1020-1, No GLP, Not published
Guideline(s):	FOCUS (2014)
Deviations:	No
GLP:	No
Acceptability:	Yes

Materials and methods

The dissipation of zoxamide was studied based on residues data on/in salad plants in the field in Southern Europe (Italy) and in the greenhouse. The studies on "open head" lettuce, rocket salad, endive and escarole were already evaluated and regarded valid by EFSA (2016)[5] for the modification of maximum residue levels (MRLs) of Zoxamide in the crop groups 'lettuces and salad plants', 'spinaches and similar leaves' and 'herbs and edible flowers'

In a study report by Luciani G.P. (2012; report no. AGRI 013/12 GLP DEC, Doc. No. 644-007, KCP 9.2.5/04) in total four decline trials on lettuce, rocket salad and endive were performed in season 2012 in double in the open field at four different locations in Italy, Southern Europe. In these trials, zoxamide was applied twice with a Knapsack sprayer at nominally 180 g/ha as either Zoxium 240 SC (an SC

[5] EFSA (2016): Reasoned opinion on the modification of the existing maximum residue levels for zoxamide in various leafy crops. EFSA Journal 2016;14 (7): 4527, 13 pp.

formulation containing nominally 240 g/L Zoxamide) or GWN-9963 (SC formulation containing nominally 180 g/L of each zoxamide and dimethomorph) at an interval of 8 ±1 days during crop growth stages BBCH 45–46. One control plot was left untreated.

In a study report by Luciani G.P. (2012; report no. AGRI 014/12 GLP DEC, Doc. No. 644-008, KCP 9.2.5/05) in total four decline trials on lettuce, rocket salad and escarole were performed in 2012 in double under greenhouse conditions. In these trials, Zoxamide was applied twice with a Knapsack sprayer at nominally 180 g/ha with either Zoxium 240 SC (an SC formulation containing nominally 240 g/L Zoxamide) or GWN-9963 (SC formulation containing nominally 180 g/L of each zoxamide and dimethomorph) at an interval of 8 ±1 days during crop growth stages BBCH 14-41. One control plot per trial was left untreated.

In both studies the leaves were analysed 0, 3, 7, 10 and 14 days after the last application with a method validated according to SANCO/825/00 rev. 8.1 (2010) and proved to be fit for purpose during EU MRL evaluation (EFSA, 2016).

Table A 2-16: Zoxamide residues on salad plants; Southern EU open field trials* [mg/kg]

Study no.	RA 12 058BPL IT 01		RA 12 058BPL IT 02		RA 12 058BPL IT 03		RA 12 058BPL IT 04	
Day	Lettuce Trocadero (1)	Lettuce Trocadero (2)	Lettuce Trocadero (3)	Lettuce Trocadero (4)	Rocket salad Selvatica (1)	Rocket salad Selvatica (2)	Endive Quintana (1)	Endive Quintana (2)
0	8.24	8.72	12.07	9.53	21.26	23.34	5.65	5.02
3	5.05	6.74	6.79	4.2	8.86	16.77	5.35	3.97
7	4.44	3.49	4.66	3.99	7.45	9.46	3.18	2.91
10	2.18	2.28	2.54	3.36	7.41	8.62	2.33	2.71
14	0.78	1.03	1.02	2.21	5.5	6.11	2.05	2.28

* Doc. No. 644-007, KCP 9.2.5/04

Table A 2-17: Zoxamide residues on salad plants; indoor trials [mg/kg]**

Study no.	R03AG12-01		R03AG12-02		R03AG12-03		R03AG12-04	
Day	Lettuce Maximus (1)	Lettuce Maximus (2)	Lettuce Fabietto (1)	Lettuce Fabietto (2)	Rocket salad Broadleaf (1)	Rocket salad Broadleaf (2)	Escarole Arlonia (1)	Escarole Arlonia (2)
0	38.69	35.9	36.87	39.84	27.13	30.43	47.01	29.14
3	15.85	29.99	18.4	32.63	21.49	15	37.59	18.82
7	5.54	6.4	6.43	7.55	10.73	5.82	6.16	16.24
10	4.81	5.71	5.06	5.94	5.48	4.6	4.96	4.95
14	1.34	0.88	4.39	2.38	5.01	3.9	4.45	2.44

** Doc. No. 644-008, KCP 9.2.5/05

Based on the evaluated field residues data, rate constants and DT_{50} values for zoxamide were calculated with the computer software CAKE version 3.4 (Tessella, 2020). The kinetic models considered for the analysis were "Single First Order" (SFO), "Double First Order in Parallel" (DFOP), "Hockey Stick (HS), and "First Order Multi Compartment" (FOMC). The evaluation of the kinetic data was performed as follows :

1. The best kinetic model was identified primarily using the statistical goodness of fit Chi² (X^2).
2. Additionally, the coefficient of determination (r^2) was used if no distinction could be made based on Chi².
3. Finally, the visual fit was considered if no distinction could be made based on chi² and r^2.

Results and discussions

Open field data

Results of residue dissipation data for zoxamide from salad plants growing in the open field under Southern EU (Italian) conditions are summarised in the following Table. The best kinetic models/fits are indicated in **bold**.

Table A 2-18: Results of CAKE calculations for all kinetic models - Zoxamide residue dissipation data on/in salad plants in the Southern EU (Italy)

	Field trial no.	Crop	Kinetics	X^2 [%]	r^2	DT_{50} [d]	DT_{90} [d]
Open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04	RA 12 058BPL IT 01	Lettuce Trocadero (1)	**SFO**	**11.7**	**0.9452**	**5.53**	**18.4**
			DFOP	16.7	0.9452	5.53	18.4
			HS	16.7	0.9452	5.53	62.5
			FOMC	13.4	0.9451	5.53	18.4
		Lettuce Trocadero (2)	**SFO**	**6.79**	**0.9834**	**5.22**	**17.3**
			DFOP	9.69	0.9834	5.22	17.3
			HS	9.69	0.9834	5.22	47.1
			FOMC	7.77	0.9834	5.21	17.3
	RA 12 058BPL IT 02	Lettuce Trocadero (3)	**SFO**	**6.65**	**0.9864**	**4.44**	**14.8**
			DFOP	7.99	0.9906	4.08	15.7
			HS	8.9	0.9881	4.59	13.4
			FOMC	7.52	0.9867	4.31	15.3
		Lettuce Trocadero (4)	SFO	17.4	0.8451	6.01	20
			DFOP	6.58	0.9888	1.59	33.9
			HS*	**6.58**	**0.9888**	**1.79**	**33.9**
			FOMC	7.61	0.9765	2.38	399
	RA 12 058BPL IT 03	Rocket salad Selvatica (1)	SFO	19.9	0.8134	5.66	18.8
			DFOP	3.63	0.9968	0.365	40.4
			HS*	**3.63**	**0.9968**	**2.34**	**40.4**
			FOMC	4.01	0.9939	1.52	973
		Rocket salad Selvatica (2)	SFO	5.25	0.9827	6.54	21.7
			DFOP	5.28	0.9911	5.84	>10,000
			HS	**3.46**	**0.9962**	**5.66**	**29.3**
			FOMC	4.55	0.9897	5.95	30.1
	RA 12 058BPL IT 04	Endive Quintana (1)	**SFO**	**8.14**	**0.9374**	**8.53**	**28.3**
			DFOP	11.6	0.9374	8.53	28.3
			HS	11.4	0.9403	8.2	125
			FOMC	9.31	0.9373	8.53	28.4
		Endive Quintana (2)	SFO	4.07	0.9703	11.4	37.8
			DFOP	2.32	0.9952	11.1	>10,000
			HS	**1.09**	**0.9989**	**11.6**	**58.2**

	Field trial no.	Crop	Kinetics	X^2 [%]	r^2	DT_{50} [d]	DT_{90} [d]
			FOMC	2.08	0.994	11.2	155

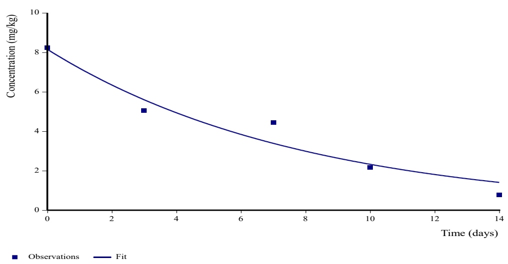
* Selected based on visual fit since no distinction could be found based on chi² and r² for DFOP and HS. The selection also represents the worst-case.

For all salad varieties in the open field trials the X^2-values for the best fit models were < 15% and the coefficients of determination (r^2) ≥ 0.94. As a result, the correspondence between the model predictions and the observed data is good for all data sets. Hence, the calculated DT_{50} values are reliable.

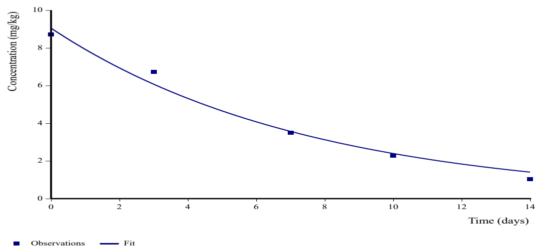
For lettuce Trocadero (1), lettuce Trocadero (2), lettuce Trocadero (3) and endive Quintana (1) minimum X^2-values were found for SFO kinetics. The choice of kinetics was confirmed by the good visual fits (see Figure A 6:, demonstrating good visual fits for the best fit kinetics).

RA 12 058BPL IT 01

Lettuce Trocadero (1) (SFO)

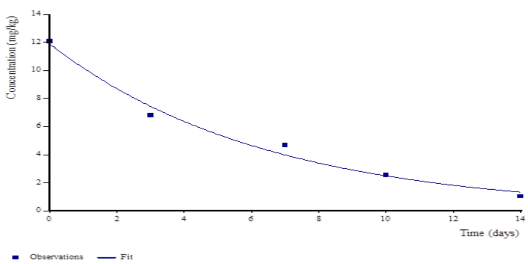


Lettuce Trocadero (2) (SFO)

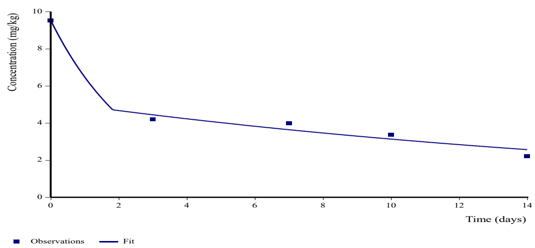


RA 12 058BPL IT 02

Lettuce Trocadero (3) (SFO)

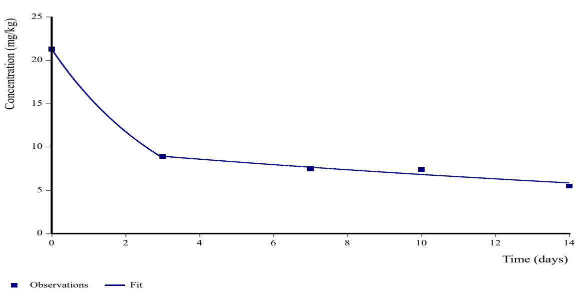


Lettuce Trocadero (4) (HS)

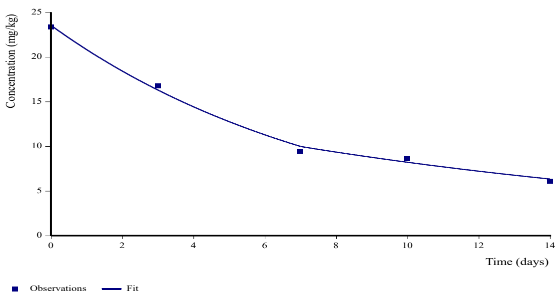


RA 12 058BPL IT 03

Rocket salad Selvatica (1) (HS)



Rocket salad Selvatica (2) (HS)



RA 12 058BPL IT 04

Endive Quintana (1) (SFO)

Endive Quintana (2) (HS)

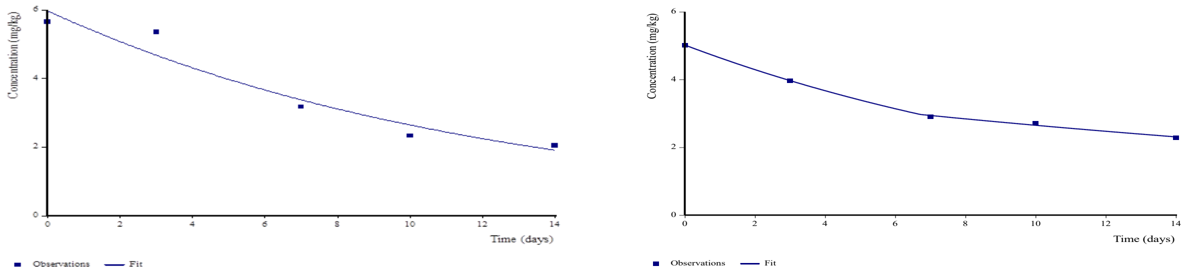


Figure A 6: **Plot with the residue decline data of Zoxamide using the best fit kinetics for each salad variety - open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04**

For Rocket salad Selvatica (1) and lettuce Trocadero (4) the kinetic models DFOP and HS are statistically even with respect to X²-statistics and the coefficient of determination. In Figure A 7: and Figure 3 the graphs for both DFOP and HS kinetics are shown, respectively. For these salad plants HS kinetics with a good visual fit were chosen to derive DT_{50} values.

Rocket salad Selvatica (1) (DFOP) Rocket salad Selvatica (1) (HS)

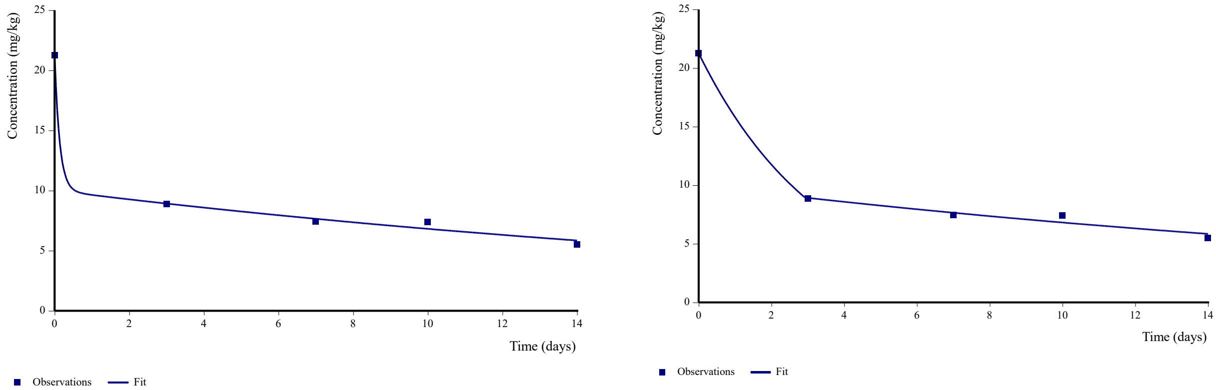


Figure A 7: Plot with the residue decline data of Zoxamide using the kinetic models DFOP (on the left side) and HS (on the right side) - rocket salad Selvatica (1), open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04

Lettuce Trocadero (4) (DFOP) Lettuce Trocadero (4) (HS)

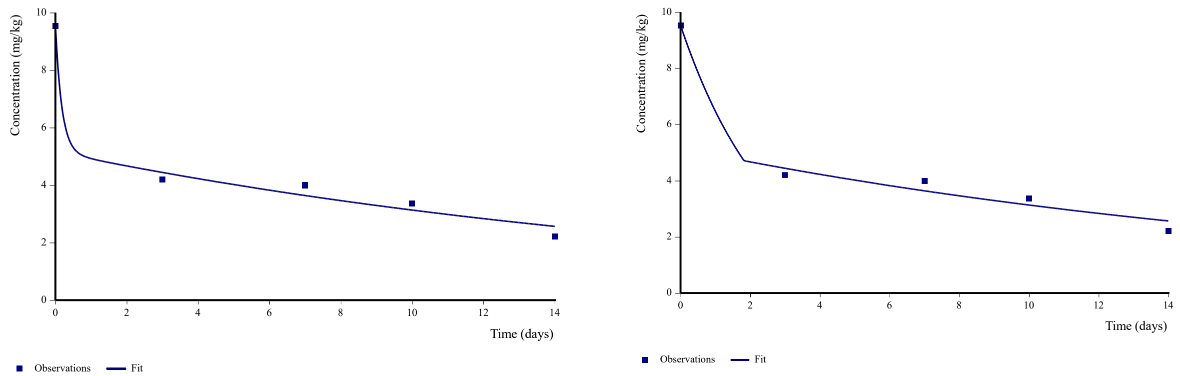


Figure A 8: Plot with the residue decline data of Zoxamide using the kinetic models DFOP (on the left side) and HS (on the right side) - lettuce Trocadero (4), open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04

In the following tables the CAKE results are presented in more detail for all different kinetics; together with DT_{50} and DT_{90} values, the values for statistical goodness of fit (X^2) and the coefficients of determination (r^2), the parameter data, as well as the lower and upper 95% confidence intervals (CI), and further information on the t-tests. Again, best fit kinetics are indicated in **bold**.

Table A 2-19: Results of CAKE calculations for all kinetic models (open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04) - RA 12 058BPL IT 01, Lettuce Trocadero (1)

Model	**SFO**	DFOP	HS	FOMC
DT_{50} [days]	**5.53**	5.53	5.53	5.53
DT_{90} [days]	**18.4**	18.4	62.5	18.4
X^2 [%]	**11.7**	16.7	16.7	13.4
r^2	**0.9452**	0.9452	0.9452	0.9451
Parameter	k = 0.1254 $M_{(0)}$ = 8.152	k1 = 0.1254 k2 = 0.01738 g = 1 $M_{(0)}$ = 8.152	k1 = 0.1254 k2 = 0.008697 tb = 15.07 $M_{(0)}$ = 8.152	α = 1590 β = 12700 $M_{(0)}$ = 8.152
Lower Cl (95%)	k = 0.05406 $M_{(0)}$ = 5.883	k1 = -0.3562 k2 = nd g = nd $M_{(0)}$ = -7.42	k1 = -0.3562 k2 = nd tb = nd $M_{(0)}$ = -7.42	α = -19880 β = -157200 $M_{(0)}$ = 4.419
Upper Cl (95%)	k =0.197 $M_{(0)}$ = 10.42	k1 = 0.607 k2 = nd g = nd $M_{(0)}$ = 23.72	k1 = 0.607 k2 = nd tb = nd $M_{(0)}$ = 23.72	α = 23100 β = 183000 $M_{(0)}$ = 11.89
t-test	p(k) = 0.005645	p(k1) = 0.09343 p(k2) = nd	p(k1) = 0.09343 p(k2) = nd	-

Table A 2-20: Results of CAKE calculations for all kinetic models (open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04) - RA 12 058BPL IT 01, Lettuce Trocadero (2)

Model	**SFO**	DFOP	HS	FOMC
DT_{50} [days]	**5.22**	5.22	5.22	5.21
DT_{90} [days]	**17.3**	17.3	47.1	17.3
X^2 [%]	**6.79**	9.69	9.69	7.77
r^2	**0.9834**	0.9834	0.9834	0.9834
Parameter	k =0.1329 $M_{(0)}$ = 9.048	k1 = 0.1329 k2 = 0.01263 g = 1 $M_{(0)}$ = 9.048	k1 = 0.1329 k2 = 0.0117 tb = 14.46 $M_{(0)}$ = 9.048	α = 1270 β = 9570 $M_{(0)}$ = 9.048
Lower Cl (95%)	k =0.09039 $M_{(0)}$ = 7.62	k1 = -0.1498 k2 = nd g = nd $M_{(0)}$ = -0.7127	k1 = -0.111 k2 = -3.532 tb = 10.87 $M_{(0)}$ = 5.731	α = nd β = nd $M_{(0)}$ = 6.708
Upper Cl (95%)	k =0.175 $M_{(0)}$ = 10.48	k1 = 0.416 k2 = nd g = nd $M_{(0)}$ = 18.81	k1 = 0.377 k2 = 3.556 tb = 18.04 $M_{(0)}$ = 12.37	α = nd β = nd $M_{(0)}$ = 11.39
t-test	p(k) = 0.00108	p(k1) = 0.05279 p(k2) = nd	p(k1) = 0.04566 p(k2) = 0.4867	-

Table A 2-21: Results of CAKE calculations for all kinetic models (open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04) - RA 12 058BPL IT 02, Lettuce Trocadero (3)

Model	**SFO**	DFOP	HS	FOMC
DT_{50} [days]	**4.44**	4.08	4.59	4.31
DT_{90} [days]	**14.8**	15.7	13.4	15.3
X^2 [%]	**6.65**	7.99	8.9	7.52
r^2	**0.9864**	0.9906	0.9881	0.9867
Parameter	k = 0.1561 $M_{(0)}$ = 11.87	k1 = 4.375 k2 = 0.1391 g = 0.1186 $M_{(0)}$ = 12.07	k1 = 0.1512 k2 = 0.2281 tb = 9.673 $M_{(0)}$ = 11.81	α = 11.84 β = 71.42 $M_{(0)}$ = 11.93
Lower Cl (95%)	k =0.1105 $M_{(0)}$ = 10.14	k1 = -2256000 k2 = -0.7892 g = -3.952 $M_{(0)}$ = 1.295	k1 = -0.2394 k2 = -2.942 tb = -68.59 $M_{(0)}$ = 0.2711	α = -214.2 β = -1371 $M_{(0)}$ = 8.926
Upper Cl (95%)	k =0.202 $M_{(0)}$ = 13.6	k1 = 2260000 k2 = 1.067 g = 4.189 $M_{(0)}$ = 22.84	k1 = 0.542 k2 = 3.398 tb = 87.94 $M_{(0)}$ = 23.35	α = 237.9 β = 1510 $M_{(0)}$ = 14.93
t-test	p(k) = 0.000832	p(k1) = 0.5 p(k2) = 0.154	p(k1) = 0.06386 p(k2) = 0.2643	-

Table A 2-22: Results of CAKE calculations for all kinetic models (open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04) - RA 12 058BPL IT 02, Lettuce Trocadero (4)

Model	SFO	DFOP	**HS**	FOMC
DT_{50} [days]	6.01	1.59	**1.79**	2.38
DT_{90} [days]	20	33.9	**33.9**	399
X^2 [%]	17.4	6.58	**6.58**	7.61
r^2	0.8451	0.9888	**0.9888**	0.9765
Parameter	k =0.1154 $M_{(0)}$ = 8.585	k1 = 5.527 k2 = 0.04983 g = 0.4588 $M_{(0)}$ = 9.53	k1 = 0.3869 k2 = 0.04983 tb = 1.822 $M_{(0)}$ = 9.53	α = 0.3219 β = 0.3123 $M_{(0)}$ = 9.526
Lower Cl (95%)	k =0.01038 $M_{(0)}$ = 4.827	k1 = -4557 k2 = -0.2229 g = -0.7982 $M_{(0)}$ = 1.9	k1 = -100700 k2 = -0.2706 tb = -544100 $M_{(0)}$ = 1.901	α = -0.4731 β = -2.214 $M_{(0)}$ = 6.886
Upper Cl (95%)	k =0.22 $M_{(0)}$ = 12.34	k1 = 4570 k2 = 0.323 g = 1.716 $M_{(0)}$ = 17.16	k1 = 101000 k2 = 0.37 tb = 544000 $M_{(0)}$ = 17.16	α = 1.117 β = 2.839 $M_{(0)}$ = 12.17
t-test	p(k) = 0.01978	p(k1) = 0.4951 p(k2) = 0.1295	p(k1) = 0.5 p(k2) = 0.1491	-

Table A 2-23: Results of CAKE calculations for all kinetic models (open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04) - RA 12 058BPL IT 03, Rocket salad Selvatica (1)

Model	SFO	DFOP	**HS**	FOMC
DT_{50} [days]	5.66	0.365	**2.34**	1.52
DT_{90} [days]	18.8	40.4	**40.4**	973
X^2 [%]	19.9	3.63	**3.63**	4.01
r^2	0.8134	0.9968	**0.9968**	0.9939
Parameter	k =0.1224 $M_{(0)}$ = 18.96	k1 = 7.362 k2 = 0.03838 g = 0.5294 $M_{(0)}$ = 21.26	k1 = 0.2963 k2 = 0.03838 tb = 2.922 $M_{(0)}$ = 21.26	α = 0.2516 β = 0.103 $M_{(0)}$ = 21.26
Lower Cl (95%)	k =-0.002337 $M_{(0)}$ = 9.551	k1 = -12620 k2 = -0.1175 g = -0.1109 $M_{(0)}$ = 12.14	k1 = -0.84 k2 = -0.1172 tb = -9.536 $M_{(0)}$ = 14.98	α = -0.122 β = -0.5488 $M_{(0)}$ = 18.24
Upper Cl (95%)	k =0.247 $M_{(0)}$ = 28.37	k1 = 12600 k2 = 0.194 g = 1.17 $M_{(0)}$ = 30.38	k1 = 1.433 k2 = 0.194 tb = 15.38 $M_{(0)}$ = 27.54	α = 0.625 β = 0.755 $M_{(0)}$ = 24.27
t-test	p(k) = 0.02618	p(k1) = 0.4976 p(k2) = 0.09849	p(k1) = 0.0933 p(k2) = 0.09832	-

Table A 2-24: Results of CAKE calculations for all kinetic models (open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04) - RA 12 058BPL IT 03, Rocket salad Selvatica (2)

Model	SFO	DFOP	**HS**	FOMC
DT_{50} [days]	6.54	5.84	**5.66**	5.95
DT_{90} [days]	21.7	>10,000	**29.3**	30.1
X^2 [%]	5.25	5.28	**3.46**	4.55
r^2	0.9827	0.9911	**0.9962**	0.9897
Parameter	k =0.106 $M_{(0)}$ = 23.05	k1 = 0.1581 k2 = $5.72E^{-18}$ g = 0.8291 $M_{(0)}$ = 23.51	k1 = 0.1225 k2 = 0.06483 tb = 7.013 $M_{(0)}$ = 23.53	α = 2.134 β = 15.51 $M_{(0)}$ = 23.49
Lower Cl (95%)	k =0.07561 $M_{(0)}$ = 19.93	k1 = -3.463 k2 = -6.391 g = -21.02 $M_{(0)}$ = 6.647	k1 = -0.1033 k2 = -0.4159 tb = -47.21 $M_{(0)}$ = 12.72	α = -6.473 β = -63.28 $M_{(0)}$ = 19.18
Upper Cl (95%)	k =0.136 $M_{(0)}$ = 26.16	k1 = 3.78 k2 = 6.391 g = 22.68 $M_{(0)}$ = 40.38	k1 = 0.348 k2 = 0.546 tb = 61.24 $M_{(0)}$ = 34.34	α = 10.74 β = 94.29 $M_{(0)}$ = 27.81
t-test	p(k) = 0.000785	p(k1) = 0.3388 p(k2) = 0.5	p(k1) = 0.04586 p(k2) = 0.1681	-

Table A 2-25: Results of CAKE calculations for all kinetic models (open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04) - RA 12 058BPL IT 04, Endive Quintana (1)

Model	**SFO**	DFOP	HS	FOMC
DT_{50} [days]	**8.53**	8.53	8.2	8.53
DT_{90} [days]	**28.3**	28.3	125	28.4
X^2 [%]	**8.14**	11.6	11.4	9.31
r^2	**0.9374**	0.9374	0.9403	0.9373
Parameter	k =0.08127 $M_{(0)}$ = 5.968	k1 = 0.08127 k2 = 0.01214 g = 1 $M_{(0)}$ = 5.968	k1 = 0.08453 k2 = 0.01109 tb = 12.51 $M_{(0)}$ = 6.002	α = 213.7 β = 2620 $M_{(0)}$ = 5.969
Lower Cl (95%)	k =0.03788 $M_{(0)}$ = 4.614	k1 = -0.2145 k2 = nd g = nd $M_{(0)}$ = -3.339	k1 = -0.3243 k2 = -37.88 tb = -810.3 $M_{(0)}$ = -4.41	α = -1852 β = -22690 $M_{(0)}$ = 3.738
Upper Cl (95%)	k =0.125 $M_{(0)}$ = 7.322	k1 = 0.377 k2 = nd g = nd $M_{(0)}$ = 15.28	k1 = 0.493 k2 = 37.9 tb = 835.3 $M_{(0)}$ = 16.42	α = 2280 β = 27900 $M_{(0)}$ = 8.2
t-test	p(k) = 0.004724	p(k1) = 0.08879 p(k2) = nd	p(k1) = 0.1158 p(k2) = 0.4988	-

Table A 2-26: Results of CAKE calculations for all kinetic models (open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04) - RA 12 058BPL IT 04, Endive Quintana (2)

Model	SFO	DFOP	**HS**	FOMC
DT_{50} [days]	11.4	11.1	**11.6**	11.2
DT_{90} [days]	37.8	>10,000	**58.2**	155
X^2 [%]	4.07	2.32	**1.09**	2.08
r^2	0.9703	0.9952	**0.9989**	0.994
Parameter	k =0.06085 $M_{(0)}$ = 4.877	k1 = 0.1472 k2 = 2.27E-12 g = 0.6222 $M_{(0)}$ = 5.034	k1 = 0.07823 k2 = 0.03454 tb = 6.709 $M_{(0)}$ = 5.02	α = 0.7394 β = 7.203 $M_{(0)}$ = 5.036
Lower Cl (95%)	k =0.04023 $M_{(0)}$ = 4.278	k1 = -2.65 k2 = -1.784 g = -13.47 $M_{(0)}$ = 3.09	k1 = -0.02027 k2 = -0.03774 tb = -7.925 $M_{(0)}$ = 4.1	α = -0.5382 β = -11.69 $M_{(0)}$ = 4.517
Upper Cl (95%)	k =0.081 $M_{(0)}$ = 5.477	k1 = 2.945 k2 = 1.784 g = 14.71 $M_{(0)}$ = 6.978	k1 = 0.177 k2 = 0.107 tb = 21.34 $M_{(0)}$ = 5.94	α = 2.017 β = 26.09 $M_{(0)}$ = 5.555
t-test	p(k) = 0.001279	p(k1) = 0.3124 p(k2) = 0.5	p(k1) = 0.03144 p(k2) = 0.05196	-

Indoor data

Results of residue dissipation data for Zoxamide from salad plants growing in the greenhouse are summarised in the following table. The best kinetic models/fits are indicated in **bold**. As explained previously, the best kinetic model was identified using primarily the statistical goodness of fit Chi Square (X^2).

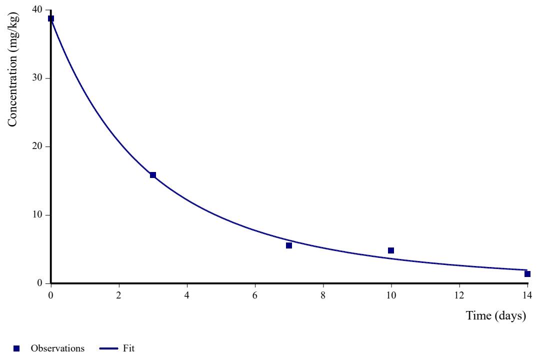
Table A 2-27: Results of CAKE calculations for all kinetic models - Zoxamide residue dissipation data on/in salad plants indoor

	Field trial no.	Crop	Kinetics	X^2 [%]	r^2	DT_{50} [d]	DT_{90} [d]
Open field, Southern EU, Doc. No. 644-007, KCP 9.2.5/04	R03AG12-01	Lettuce Maximus (1)	SFO	7.06	0.994	2.55	8.47
			DFOP	5.8	0.9976	2.25	9.66
			HS	5.09	0.9981	2.33	9.89
			FOMC	**4.75**	**0.9974**	**2.24**	**9.6**
		Lettuce Maximus (2)	**SFO**	**21.5**	**0.9163**	**3.87**	**12.9**
			DFOP	30.6	0.9163	3.87	12.9
			HS	29.3	0.9202	4.18	10.9
			FOMC	24.5	0.9163	3.87	12.9
	R03AG12-02	Lettuce Fabietto (1)	SFO	8.22	0.9887	3.15	10.5
			DFOP	6.08	0.9963	2.77	14.1
			HS	**2.23**	**0.9995**	**2.89**	**18.8**
			FOMC	6.77	0.9929	2.76	12.3
		Lettuce Fabietto (2)	**SFO**	**19.3**	**0.926**	**3.92**	**13**
			DFOP	27.6	0.926	3.92	13
			HS	27.6	0.926	3.92	13
			FOMC	22.1	0.926	3.92	13
	R03AG12-03	Rocket salad Broadleaf (1)	**SFO**	**8.94**	**0.9692**	**5.22**	**17.3**
			DFOP	12.8	0.9692	5.22	17.3
			HS	12.5	0.9708	5.11	70.9
			FOMC	10.2	0.9692	5.22	17.3
		Rocket salad Broadleaf (2)	SFO	8.72	0.9867	3.27	10.9
			DFOP	4.36	0.9979	2.78	>10,000
			HS	**0.0648**	**1**	**2.94**	**20**
			FOMC	5.67	0.9946	2.74	13.6
	R03AG12-04	Escarole Arlonia (1)	**SFO**	**22.1**	**0.9116**	**3.64**	**12.1**
			DFOP	31.5	0.9116	3.64	12.1
			HS	31.4	0.9132	3.6	12
			FOMC	25.2	0.9116	3.64	12.1
		Escarole Arlonia(2)	**SFO**	**14.8**	**0.9277**	**5.15**	**17.1**
			DFOP	21.1	0.9277	5.15	17.1
			HS	21.1	0.9277	5.15	52.8
			FOMC	16.9	0.9277	5.15	17.1

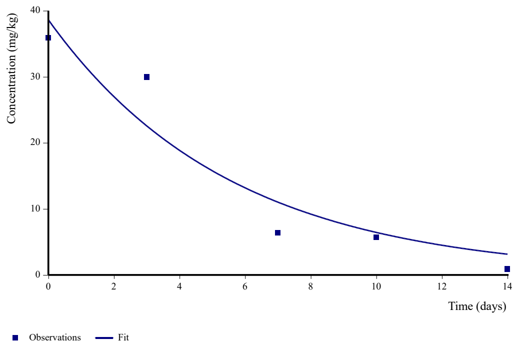
For all salad varieties in the greenhouse the X^2-values for the best fit models were < 15% except for three species: Lettuce Maximus (2), Lettuce Fabietto (2) and Escarole Arlonia (1). However, the coefficients of determination (r^2) were always > 0.91 and the visual fits for the chosen kinetics were good (see Figure).

R03AG12-01

Lettuce Maximus (1) (HS)

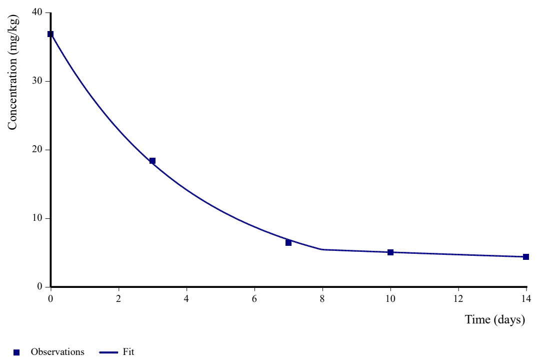


Lettuce Maximus (2) (SFO)

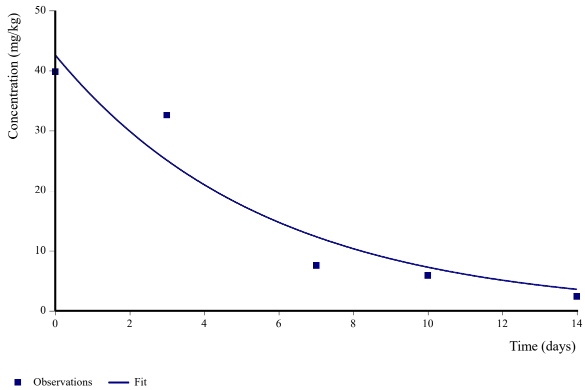


R03AG12-02

Lettuce Fabietto (1) (HS)

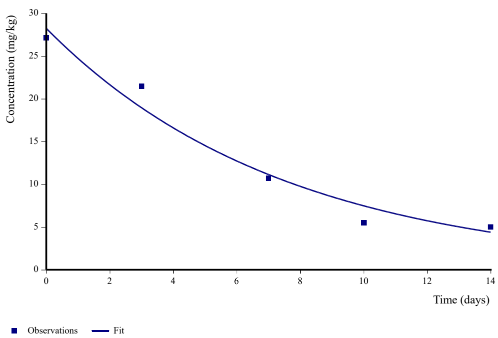


Lettuce Fabietto (2) (SFO)

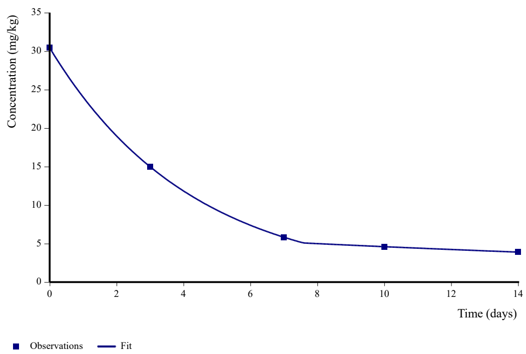


R03AG12-03

Rocket Broadleaf (1) (SFO)



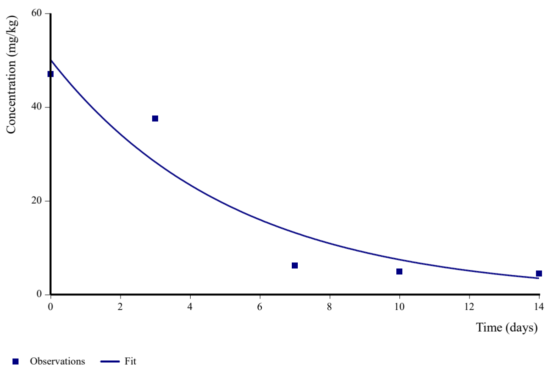
Rocket Broadleaf (2) (HS)



R03AG12-04

Escarole Arlonia (1) (SFO)

Escarole Arlonia (2) (SFO)



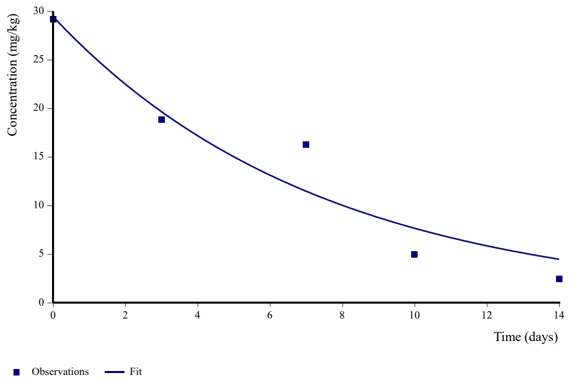


Figure A 9: **Plot with the residue decline data of Zoxamide using the best fit kinetics for each salad variety - indoor, Doc. No. 644-008, KCP 9.2.5/05**

In the following tables the CAKE results are presented in more detail for all different kinetics; together with the DT_{50} values, the values for statistical goodness of fit (X^2) and the coefficients of determination (r^2), the parameter data, as well as the lower and upper 95 % confidence intervals (CI), and further information on the t-tests. Again, best fit kinetics are indicated in **bold**.

Table A 2-28: **Results of CAKE calculations for all kinetic models (indoor, Doc. No. 644-008, KCP 9.2.5/05) - R03AG12-01, Lettuce Maximus (1)**

Model	SFO	DFOP	HS	**FOMC**
DT_{50} [days]	2.55	2.25	2.33	**2.24**
DT_{90} [days]	8.47	9.66	9.89	**9.6**
X^2 [%]	7.06	5.8	5.09	**4.75**
r^2	0.994	0.9976	0.9981	**0.9974**
Parameter	k =0.2718 $M_{(0)}$ = 38.33	k1 = 0.4348 k2 = 0.1402 g = 0.6507 $M_{(0)}$ = 38.71	k1 = 0.2975 k2 = 0.1468 tb = 5.651 $M_{(0)}$ = 38.69	α = 3.378 β = 9.822 $M_{(0)}$ = 38.7
Lower Cl (95%)	k =0.1979 $M_{(0)}$ = 33.62	k1 = -4.469 k2 = -2.259 g = -9.88 $M_{(0)}$ = 19.59	k1 = -0.08433 k2 = -0.9247 tb = -22.51 $M_{(0)}$ = 21.89	α = -4.899 β = -20.17 $M_{(0)}$ = 34.02
Upper Cl (95%)	k =0.346 $M_{(0)}$ = 43.05	k1 = 5.338 k2 = 2.54 g = 11.18 $M_{(0)}$ = 57.82	k1 = 0.679 k2 = 1.218 tb = 33.81 $M_{(0)}$ = 55.49	α = 11.66 β = 39.82 $M_{(0)}$ = 43.38
t-test	p(k) = 0.000671	p(k1) = 0.231 p(k2) = 0.2967	p(k1) = 0.03204 p(k2) = 0.166	-

Table A 2-29: Results of CAKE calculations for all kinetic models (indoor Doc. No. 644-008, KCP 9.2.5/05) - R03AG12-01, Lettuce Maximus (2)

Model	**SFO**	DFOP	HS	FOMC
DT_{50} [days]	**3.87**	3.87	4.18	3.87
DT_{90} [days]	**12.9**	12.9	10.9	12.9
X^2 [%]	**21.5**	30.6	29.3	24.5
r^2	**0.9163**	0.9163	0.9202	0.9163
Parameter	k =0.1792 $M_{(0)}$ = 38.62	k1 = 0.1792 k2 = 0.01694 g = 1 $M_{(0)}$ = 38.62	k1 = 0.1657 k2 = 0.4675 tb = 9.188 $M_{(0)}$ = 38.24	α = 13100 β = 73100 $M_{(0)}$ = 38.62
Lower Cl (95%)	k =0.02463 $M_{(0)}$ = 22.12	k1 = -0.7862 k2 = nd g = nd $M_{(0)}$ = -72.96	k1 = -1.068 k2 = -32.6 tb = -114.6 $M_{(0)}$ = -72.91	α = -14200 β = -62260 $M_{(0)}$ = 11.92
Upper Cl (95%)	k =0.334 $M_{(0)}$ = 55.12	k1 = 1.145 k2 = nd g = nd $M_{(0)}$ = 150.2	k1 = 1.399 k2 = 33.54 tb = 133 $M_{(0)}$ = 149.4	α = 40400 β = 208000 $M_{(0)}$ = 65.31
t-test	p(k) = 0.01726	p(k1) = 0.1277 p(k2) = nd	p(k1) = 0.1688 p(k2) = 0.4434	-

Table A 2-30: Results of CAKE calculations for all kinetic models (indoor, Doc. No. 644-008, KCP 9.2.5/05) - R03AG12-02, Lettuce Fabietto (1)

Model	SFO	DFOP	**HS**	FOMC
DT_{50} [days]	3.15	2.77	**2.89**	2.76
DT_{90} [days]	10.5	14.1	**18.8**	12.3
X^2 [%]	8.22	6.08	**2.23**	6.77
r^2	0.9887	0.9963	**0.9995**	0.9929
Parameter	k =0.2201 $M_{(0)}$ = 36.55	k1 = 0.2846 k2 = 3.39E^{-09} g = 0.9164 $M_{(0)}$ = 37.06	k1 = 0.2402 k2 = 0.03551 tb = 7.985 $M_{(0)}$ = 36.98	α = 2.952 β = 10.44 $M_{(0)}$ = 37
Lower Cl (95%)	k =0.1471 $M_{(0)}$ = 30.74	k1 = -1.533 k2 = -3.838 g = -3.747 $M_{(0)}$ = 15.55	k1 = 0.1193 k2 = -0.5593 tb = -4.994 $M_{(0)}$ = 29.23	α = -7.542 β = -36.53 $M_{(0)}$ = 29.84
Upper Cl (95%)	k =0.293 $M_{(0)}$ = 42.36	k1 = 2.102 k2 = 3.838 g = 5.58 $M_{(0)}$ = 58.57	k1 = 0.361 k2 = 0.63 tb = 20.96 $M_{(0)}$ = 44.74	α = 13.45 β = 57.42 $M_{(0)}$ = 44.16
t-test	p(k) = 0.001201	p(k1) = 0.1482 p(k2) = 0.5	p(k1) = 0.0126 p(k2) = 0.2934	-

Table A 2-31: Results of CAKE calculations for all kinetic models (indoor, Doc. No. 644-008, KCP 9.2.5/05) - R03AG12-02, Lettuce Fabietto (2)

Model	**SFO**	DFOP	HS	FOMC
DT_{50} [days]	**3.92**	3.92	3.92	3.92
DT_{90} [days]	**13**	13	13	13
X^2 [%]	**19.3**	27.6	27.6	22.1
r^2	**0.926**	0.926	0.926	0.926
Parameter	k =0.1769 $M_{(0)}$ = 42.59	k1 = 0.1769 k2 = 0.02296 g = 1 $M_{(0)}$ = 42.59	k1 = 0.1769 k2 = 0.01007 tb = 14.31 $M_{(0)}$ = 42.59	α = 10400 β = 58600 $M_{(0)}$ = 42.59
Lower Cl (95%)	k =0.03763 $M_{(0)}$ = 25.96	k1 = -0.7067 k2 = nd g = nd $M_{(0)}$ = -70.19	k1 = -0.7065 k2 = -43.92 tb = -30.19 $M_{(0)}$ = -70.18	α = -5735 β = -4618 $M_{(0)}$ = 15.57
Upper Cl (95%)	k =0.316 $M_{(0)}$ = 59.21	k1 = 1.061 k2 = nd g = nd $M_{(0)}$ = 155.4	k1 = 1.06 k2 = 43.95 tb = 58.8 $M_{(0)}$ = 155.4	α = 26500 β = 122000 $M_{(0)}$ = 69.61
t-test	p(k) = 0.01363	p(k1) = 0.1192 p(k2) = nd	p(k1) = 0.1192 p(k2) = 0.4991	-

Table A 2-32: Results of CAKE calculations for all kinetic models (indoor, Doc. No. 644-008, KCP 9.2.5/05) - R03AG12-03, Rocket salad Broadleaf (1)

Model	SFO	DFOP	HS	FOMC
DT_{50} [days]	**5.22**	5.22	5.11	5.22
DT_{90} [days]	**17.3**	17.3	70.9	17.3
X^2-err [%]	**8.94**	12.8	12.5	10.2
r^2	**0.9692**	0.9692	0.9708	0.9692
X^2 [%]	k =0.1328 $M_{(0)}$ = 28.23	k1 = 0.1328 k2 = 0.008087 g = 1 $M_{(0)}$ = 28.23	k1 = 0.1358 k2 = 0.01002 tb = 12.66 $M_{(0)}$ = 28.33	α = 5220 β = 39300 $M_{(0)}$ = 28.23
r^2	k =0.07658 $M_{(0)}$ = 22.34	k1 = -0.2451 k2 = nd g = nd $M_{(0)}$ = -12.2	k1 = -0.2788 k2 = nd tb = nd $M_{(0)}$ = -11.71	α = nd β = nd $M_{(0)}$ = 18.54
Parameter	k =0.189 $M_{(0)}$ = 34.13	k1 = 0.511 k2 = nd g = nd $M_{(0)}$ = 68.67	k1 = 0.55 k2 = nd tb = nd $M_{(0)}$ = 68.37	α = nd β = nd $M_{(0)}$ = 37.93
t-test	p(k) = 0.00244	p(k1) = 0.07013 p(k2) = nd	p(k1) = 0.07508 p(k2) = nd	-

Table A 2-33: Results of CAKE calculations for all kinetic models (indoor, Doc. No. 644-008, KCP 9.2.5/05) - R03AG12-03, Rocket salad Broadleaf (2)

Model	SFO	DFOP	**HS**	FOMC
DT_{50} [days]	3.27	2.78	**2.94**	2.74
DT_{90} [days]	10.9	>10,000	**20**	13.6
X^2 [%]	8.72	4.36	**0.0648**	5.67
r^2	0.9867	0.9979	**1**	0.9946
Parameter	k = 0.2123 $M_{(0)}$ = 30	k1 = 0.292 k2 = 1.99 E^{-15} g = 0.8995 $M_{(0)}$ = 30.54	k1 = 0.236 k2 = 0.04127 tb = 7.582 $M_{(0)}$ = 30.43	α = 2.208 β = 7.424 $M_{(0)}$ = 30.51
Lower Cl (95%)	k =0.1367 $M_{(0)}$ = 24.84	k1 = -1.056 k2 = -2.249 g = -2.346 $M_{(0)}$ = 17.57	k1 = 0.2325 k2 = 0.02505 tb = 7.195 $M_{(0)}$ = 30.24	α = -3.195 β = -17.16 $M_{(0)}$ = 25.47
Upper Cl (95%)	k =0.288 $M_{(0)}$ = 35.16	k1 = 1.64 k2 = 2.249 g = 4.145 $M_{(0)}$ = 43.51	k1 = 0.24 k2 = 0.057 tb = 7.969 $M_{(0)}$ = 30.62	α = 7.612 β = 32.01 $M_{(0)}$ = 35.55
t-test	p(k) = 0.00148	p(k1) = 0.1109 p(k2) = 0.5	p(k1) = 0.000375 p(k2) = 0.009845	-

Table A 2-34: Results of CAKE calculations for all kinetic models (indoor, Doc. No. 644-008, KCP 9.2.5/05) - R03AG12-04, Escarole Arlonia (1)

Model	**SFO**	DFOP	HS	FOMC
DT_{50} [days]	**3.64**	3.64	3.6	3.64
DT_{90} [days]	**12.1**	12.1	12	12.1
X^2 [%]	**22.1**	31.5	31.4	25.2
r^2	**0.9116**	0.9116	0.9132	0.9116
Parameter	k =0.1905 $M_{(0)}$ = 50.1	k1 = 0.1905 k2 = 0.01585 g = 1 $M_{(0)}$ = 50.1	k1 = 0.1927 k2 = 0.01005 tb = 12.49 $M_{(0)}$ = 50.18	α = 3380 β = 17700 $M_{(0)}$ = 50.1
Lower Cl (95%)	k =0.02287 $M_{(0)}$ = 28.42	k1 = -0.8748 k2 = nd g = nd $M_{(0)}$ = -97.2	k1 = -0.9219 k2 = -173.3 tb = -1399 $M_{(0)}$ = -97.03	α = nd β = nd $M_{(0)}$ = 14.83
Upper Cl (95%)	k =0.358 $M_{(0)}$ = 71.79	k1 = 1.256 k2 = nd g = nd $M_{(0)}$ = 197.4	k1 = 1.307 k2 = 173.4 tb = 1420 $M_{(0)}$ = 197.4	α = nd β = nd $M_{(0)}$ = 85.37
t-test	p(k) = 0.01817	p(k1) = 0.132 p(k2) = nd	p(k1) = 0.136 p(k2) = 0.4998	-

Table A 2-35: Results of CAKE calculations for all kinetic models (indoor, Doc. No. 644-008, KCP 9.2.5/05) - R03AG12-04, Escarole Arlonia (2)

Model	**SFO**	DFOP	HS	FOMC
DT_{50} [days]	**5.15**	5.15	5.15	5.15
DT_{90} [days]	**17.1**	17.1	52.8	17.1
X^2 [%]	**14.8**	21.1	21.1	16.9
r^2	**0.9277**	0.9277	0.9277	0.9277
Parameter	k =0.1347 $M_{(0)}$ = 29.43	k1 = 0.1347 k2 = 0.02163 g = 1 $M_{(0)}$ = 29.43	k1 = 0.1346 k2 = 0.009269 tb = 14.46 $M_{(0)}$ = 29.43	α = 2360 β = 17500 $M_{(0)}$ = 29.43
Lower Cl (95%)	k =0.04202 $M_{(0)}$ = 19.43	k1 = -0.4774 k2 = nd g = nd $M_{(0)}$ = -38.85	k1 = -0.4142 k2 = -46.58 tb = -33.29 $M_{(0)}$ = -8.674	α = -3521 β = -21430 $M_{(0)}$ = 13.08
Upper Cl (95%)	k =0.227 $M_{(0)}$ = 39.44	k1 = 0.747 k2 = nd g = nd $M_{(0)}$ = 97.71	k1 = 0.683 k2 = 46.6 tb = 62.21 $M_{(0)}$ = 67.54	α = 8240 β = 56500 $M_{(0)}$ = 45.79
t-test	p(k) = 0.009511	p(k1) = 0.1094 p(k2) = nd	p(k1) = 0.09881 p(k2) = 0.4992	-

<u>Overall</u>

The best kinetic model was identified using primarily the statistical goodness of fit Chi Square (X^2). Furthermore, the coefficient of determination (r^2) and the visual fit.

Table A 2-36: Residue dissipation of zoxamide on/in open head salad plants under southern EU field and indoor conditions

	Field trial no.	**Crop**	**Kinetics**	**X^2 [%]**	**r^2**	**DT_{50} [d]**
Open field, Southern EU *	RA 12 058BPL IT 01	Lettuce Trocadero (1)	SFO	11.7	0.9452	5.53
		Lettuce Trocadero (2)	SFO	6.79	0.9834	5.22
	RA 12 058BPL IT 02	Lettuce Trocadero (3)	SFO	6.65	0.9864	4.44
		Lettuce Trocadero (4)	HS	6.58	0.9888	1.79
	RA 12 058BPL IT 03	Rocket salad Selvatica (1)	HS	3.63	0.9968	2.34
		Rocket salad Selvatica (2)	HS	3.46	0.9962	5.66
	RA 12 058BPL IT 04	Endive Quintana (1)	SFO	8.14	0.9374	8.53
		Endive Quintana (2)	HS	1.09	0.9989	11.6
	Geometric mean half-live (n = 8) in the field ± SD					**4.8 ± 3.2**

	Field trial no.	Crop	Kinetics	X^2 [%]	r^2	DT_{50} [d]
Indoor **	R03AG12-01	Lettuce Maximus (1)	FOMC	4.75	0.9974	2.24
		Lettuce Maximus (2)	SFO	21.5	0.9163	3.87
	R03AG12-02	Lettuce Fabietto (1)	HS	2.23	0.9995	2.89
		Lettuce Fabietto (2)	SFO	19.3	0.926	3.92
	R03AG12-03	Rocket salad Broadleaf (1)	SFO	8.94	0.9692	5.22
		Rocket salad Broadleaf (2)	HS	0.0648	1	2.94
	R03AG12-04	Escarole Arlonia (1)	SFO	22.1	0.9116	3.64
		Escarole Arlonia (2)	SFO	14.8	0.9277	5.15
	Geometric mean half-live (n = 8) under glasshouse conditions ± SD					**3.6 ± 1.1**
Overall geometric mean half-live (n = 16) ± SD						**4.2 ± 2.5**

* Doc. No. 644-007, KCP 9.2.5/04
** Doc. No. 644-008, KCP 9.2.5/05

As a result of the kinetic evaluation of these residues data, zoxamide on/in salad plants decreased quickly. DT_{50} values from field decline studies were found in the range of 1.79 to 11.6 days with a geometric mean DT_{50} value (n= 8) of 4.8 (± 3.2) days. Under glasshouse conditions, zoxamide degraded on/in plants with DT_{50} values of 2.33 to 5.22 days and a geometric mean DT_{50} value (n= 8) of 3.6 (± 1.1) days. The DT_{50} values for zoxamide from the field trials show a higher variability (larger standard deviation) compared to the indoor trials. However, the half-lives of the indoor trials are in the range of the outdoor trials.

Conclusion

The overall geometric mean DT_{50} value (n=16) for zoxamide on/in salad plants grown under indoor and Southern European field conditions amounts to 4.2 (± 2.5) days. This value is regarded representative to describe the residue dissipation behaviour of zoxamide on/in dicotyledonous plants.

A 2.5 Study 5- Overall $DegT_{50}$ of Zoxamide on plants

Substance specific DT_{50} values for residue dissipation of zoxamide were taken into account for refined PEC_{SW} calculations. These values were obtained for salad plants in residues decline trials of Luciani (2012) in reports no. AGRI 013/12 GLP DEC and AGRI 014/12 GLP DEC summarised in Part B Section 7. These trials were already used for MRL setting of zoxamide in leafy crops and regarded valid (see EFSA (2016): Reasoned opinion on the modification of the existing maximum residue levels for zoxamide in various leafy crops, EFSA Journal 2016;14(7):4527, 13 pp.). The residue data were kinetically re-evaluated by Klein et al. (2020; report no. GOW1020-1).

In addition, the dissipation of zoxamide on/in surrogate dicotyledonae (i.e. sugar beet leaves) and monocotyledonae (i.e. cereals) plants has been studied by Appeltauer (2020a,b,c,d; as summarised above) in the field under Northern European and Southern European growing conditions, inclusive a kinetic evaluation of the degradation data. An overall summary and assessment of the available dissipation data of zoxamide on plants has been performed by Klein & Mendel-Kreusel (2020)

This active substance related study has already been provided to the RMS Latvia. Thus, the summary of the study is only presented for completeness' sake. The study is only indicated in the list of data submitted or referred to by the applicant and relied on.

Comments of zRMS:	The confirmatory-like studies were evaluated by the RMS-LV for zoxamide and its metabolites in an interzonal procedure. All details are to be found in the file: Zoxamide_ confirmatory_ like_data_Part_B5_B6_B8_B9_XXXX_LV_2023, Part B – Section 8, available on CIRCABC. RMS-LV conclusion: The kinetic evaluation of residue data was performed according to FOCUS (2014), therefore the RMS believes that the study is acceptable. However, the overall geomean DT50 value of 3.9 days for zox-amide is not considered appropriate for surface water (SW) modelling purposes. Both MACRO and PRZM models which are used for SW modelling considers first-order (SFO) kinetics for degrada-tion/dissipation of substances in the soil and also on the crop canopy therefore RMS believes that only DT50 values representing the same kinetics (SFO or pseudo-SFO) should be used in SWASH sell for input parameter *Half-life at crop surface*. Given the above, we believe that prior to calculating the overall geomean DT50 for zoxamide for SW modelling purposes, non-SFO DT50 values (e.g., FOMC, DFOP and HS) should been converted to pseudo-SFO DT50 values (e.g., for FOMC – DT50 = DT90/3.32, for DFOP and HS – DT50 = ln2/k2). Therefore, the RMS has done additional calculations to obtain DT50 in/on plants for zoxamide which would be appropriate for SW modelling. According to RMS calculations the appropriate modelling endpoint (overall geomean DT50 in/on plants) for zoxamide for SW modelling purposes is 5.8 days,

Reference:	**KCP 9.2.5/06 (Doc. No. 782-002)**
Report	Klein, J., Mendel-Kreusel, R., 2020: Residue dissipation of zoxamide on/in plants Gowan Crop Protection Ltd., UK Mendel-Kreusel Consult, Germany, Report No. GOW1120-1-1, No GLP, Not published
Guideline(s):	FOCUS (2014)

Deviations: No

GLP: No

Acceptability: Yes

Materials and methods

The best fit kinetic of the residue decline of zoxamide on/in plants under southern and northern European growing conditions as well as under greenhouse (indoor) conditions was analysed. Following studies were considered:

- Study S16-05375 (Doc. No. 644-003, KCP 9.2.5/07) performed by Appeltauer (2020a): Determination of residues of zoxamide on/in typical feed items of herbivorous birds and mammals after two applications of Zoxium 240 SC on sugar beet and wheat in Germany 2017
- Study S16-05376 (Doc. No. 644-005, KCP 9.2.5/08) performed by Appeltauer (2020b): Determination of residues of zoxamide on/in typical feed items of herbivorous birds and mammals after two applications of Zoxium 240 SC on sugar beet and wheat in southern Europe 2017
- Study S19-01450 (Doc. No. 644-004, KCP 9.2.5/09) performed by Appeltauer (2020c): Determination of residues of zoxamide on/in typical feed items of herbivorous birds and mammals after two applications of the test item on sugar beet and wheat in The Netherlands in 2019
- Study S19-23773 (Doc. No. 644-006, KCP 9.2.5/10) performed by Appeltauer (2020d): Determination of residues of zoxamide on/in typical feed items of herbivorous birds and mammals after two applications of the test item on sugar beet and wheat in Italy in 2020

Study S16-05375

In this study the residue declines of zoxamide on representative plants grown under Southern German (Northern European) field conditions was analysed: On sugar beet leaves (as surrogate leafy/dicotyledonae plant) and on wheat green mass (as surrogate grass-like/monocotyledonae plant). The residues and degradation kinetics of the active ingredient were investigated after two spray applications of Zoxium 240 SC (240 g/L zoxamide) at application rates for zoxamide of 180 g a.s./ha with an interval of 7 days (BBCH 14-24 for sugar beet and wheat). In the following table the residues data for zoxamide are presented. These values were used as input for the computer software KinGUII (version 2.2012) to calculate the DT_{50} values and DT_{90} values.

Table A 2-37: Zoxamide residues on sugar beet leaves and wheat green mass (S16-05375-01 to S16-05375-03; Northern EU* [mg/kg]

S16-05375-01			S16-05375-02			S16-05375-03		
Day	sugar beet leaves	wheat green mass	Day	sugar beet leaves	wheat green mass	Day	sugar beet leaves	wheat green mass
0.13	6.84	10.1	0.13	7.6	9.17	0.13	5.44	9.74
1	5.3	8.26	1	3.96	7.7	1	6.7	6.77
2	2	4.6	2	3.08	8.24	2	5.5	6.3
4	1.9	3.55	4	1.58	5.91	4	2.44	4.71
6	1.76	2.26	6	1.77	3.02	6	1.27	3.3
8	0.71	2.64	8	0.83	2.22	8	0.62	1.86
16	0.22	0.27	15	0.66	0.72	16	0.16	0.282

*Doc. No. 644-003, KCP 9.2.5/07

In general, the residues of wheat green mass are higher than the residues of sugar beet leaves. However, for both plants the residues of zoxamide are decreasing quickly.

Study S16-05376

In this study the residue declines of zoxamide on representative plants grown under Southern European (Bulgarian and Spanish) field conditions: On sugar beet green mass (as surrogate leafy/dicotyledonae plant) and on wheat green mass (as surrogate grass-like/monocotyledonae plant). The residues and degradation kinetics of the active ingredient were investigated after two spray applications of Zoxium 240 SC (240 g/L zoxamide) at each 180 g zoxamide/ha with an interval of 7 days (BBCH 22-29 of plants). In the following table the experimental results are summarised, which were used as input for the computer software KinGUII (version 2.2012) to calculate DT_{50} values and DT_{90} values.

Table A 2-38: Zoxamide residues on sugar beet leaves and wheat green mass (S16-05376-01 to S16-05376-03; Southern EU* [mg/kg]

S16-05376-01			S16-05376-02			S16-05376-03		
Day	sugar beet leaves	wheat green mass	Day	sugar beet leaves	wheat green mass	Day	sugar beet leaves	wheat green mass
0.08	9.48	7.97	0.125	10.2	7.66	0.125	6.53	5.83
1	9.11	5.56	1	11.1	5.81	1	7.55	5.37
2	9.08	5.27	2.04	10.2	5.44	2	4.83	5.23
5	1.28	1.6	4	7.53	5.59	4	1.97	3
7	1.12	1.15	7	4.31	2.42	6	1.57	2.74
8	0.78	0.39	8	3.14	4.12	8	1.49	2.74
16	0.08	0.02	16	0.69	0.51	15	0.76	2.02

*Doc. No. 644-005, KCP 9.2.5/08

In general, in trial 1 and trial 2 the residues of wheat green mass are lower than the residues of sugar beet leaves. In trial 3, wheat green mass yields a higher residue. However, for both plants the residues of zoxamide are decreasing quickly.

Study S19-01450

In this study the residue declines of zoxamide were investigated on representative plants grown under Northern European field conditions (The Netherlands): On sugar beet leaves (as surrogate leafy/dicotyledonae plant) and on wheat green mass (as surrogate grass-like/monocotyledonae plant). The residues and degradation kinetics of the active ingredient were investigated after two spray applications of Zoxium 240 SC (240 g/L zoxamide) at application rates of each 180 g zoxamide/ha with an interval of 7 days (BBCH 18-21 of plants). The following table shows the experimental results taken from Appeltauer (2020c), the concentrations of zoxamide residues on sugar beet leaves and wheat green mass, are presented. These values were used as input for the computer software KinGUII (version 2.2012) to calculate DT_{50} values and DT_{90} values.

Table A 2-39: Zoxamide residues on sugar beet leaves and wheat green mass; Northern EU * [mg/kg]

S19-01450-01			
Day	wheat green mass	Day	sugar beet leaves
0.14	6.95	0.13	7.09
1	7.43	1	7.07
2	5.96	2	6.16
4	4.69	4	5.68

5	3.55	5	4.83
7	2.51	7	4.23
14	1.82	14	3.51
21	0.85	21	1.68

* Doc. No. 644-004, KCP 9.2.5/09

In general, the residues of wheat green mass are higher than the residues of sugar beet leaves. However, for both plants the residues of zoxamide are decreasing quickly.

Study S19-23773

In this study the residue declines of zoxamide on representative plants grown under Southern European field conditions (Italy) were investigated: On sugar beet leaves (as surrogate leafy/dicotyledonae plant) and on wheat green mass (as surrogate grass-like/monocotyledonae plant). The residues and degradation kinetics of the active ingredient were investigated after two spray applications of Zoxium 240 SC (240 g/L zoxamide) at application rates for zoxamide of 180 g a.s./ha with an interval of 7 days (BBCH 17-21 of plants). The experimental result taken from Appeltauer (2020d), the concentration of zoxamide on sugar beet leaves and wheat green mass, are presented. The values in the following table were used as input for the computer software KinGUII (version 2.2012) to calculate DT_{50} and DT_{90} values.

Table A 2-40: Zoxamide residues on sugar beet leaves and wheat green mass; Southern EU * [mg/kg]

S19-23773			
Day	sugar beet leaves	Day	wheat green mass
0.12	11.4	0.11	9.58
1	8.24	1	7.97
2	6.93	2	6.98
4	7.27	4	4.64
7	5.65	7	4.06
9	3.27	9	2.3
15	2.82	15	0.941

* Doc. No. 644-006, KCP 9.2.5/10

In general, the residues of wheat green mass are lower than the residues of sugar beet leaves. However, for both plants the residues of zoxamide are decreasing quickly.

Based on the evaluated field residues data, rate constants and DT_{50} values for zoxamide were calculated. The calculation of the DT_{50} values and DT_{90} values as well as the fitting of the kinetic degradation models was done using the computer software KinGUII (version 2.2012). Four different kinetic degradation models were taken into account: single first-order, first-order multi-compartment (Gustafson & Holden, 1990), hockey stick (bi-phasic) and double first-order (bi-exponential) kinetics.

The following procedure was followed to obtain the best fit kinetics

1. The best kinetic model was identified primarily using the statistical goodness of fit Chi² (X^2).
2. Additionally, the coefficient of determination (r^2) was used if no distinction could be made based on Chi².
3. Finally, the visual fit was considered if no distinction could be made based on Chi² and r^2.

The best kinetic models/fits are indicated in **bold**.

Results and discussions

Table A 2-41: Results of calculation for all kinetic models for zoxamide on sugar beet leaves and wheat green mass; Northern EU, study S16-05375

	Crop	Field trial no.	Kinetics	X^2 [%]	r^2	DT_{50} [d]	DT_{90} [d]
Northern EU	sugar beet leaves	S16-05375-01	SFO	20.35	0.92	1.94	6.45
			FOMC	**18.02**	**0.94**	**1.43**	**8.91**
			DFOP	19.01	0.94	1.37	9.86
			HS	24.22	0.92	2.05	6.56
		S16-05375-02	SFO	19.52	0.93	1.82	6.03
			FOMC	**7.32**	**0.99**	**0.86**	**11**
			DFOP	8.68	0.99	0.93	10.15
			HS	23.23	0.93	1.82	6.04
		S16-05375-03	SFO	21.02	0.89	3.09	10.25
			FOMC	23.75	0.89	3.65	12.14
			DFOP	25.02	0.89	3.09	10.25
			HS	**10.34**	**0.98**	**3.55**	**7.79**
	wheat green mass	S16-05375-01	SFO	13.65	0.95	2.74	9.1
			FOMC	**11.42**	**0.97**	**2.07**	**12.59**
			DFOP	11.85	0.97	1.97	12.64
			HS	16.24	0.95	2.74	9.1
		S16-05375-02	**SFO**	**10.22**	**0.95**	**4.31**	**14.32**
			FOMC	11.05	0.95	4.29	14.28
			DFOP	12.16	0.95	4.31	14.32
			HS	12.16	0.95	4.31	14.32
		S16-05375-03	**SFO**	**8.04**	**0.97**	**3.65**	**12.12**
			FOMC	8.67	0.97	3.57	12.46
			DFOP	9.57	0.97	3.65	12.12
			HS	9.3	0.98	3.8	10.82

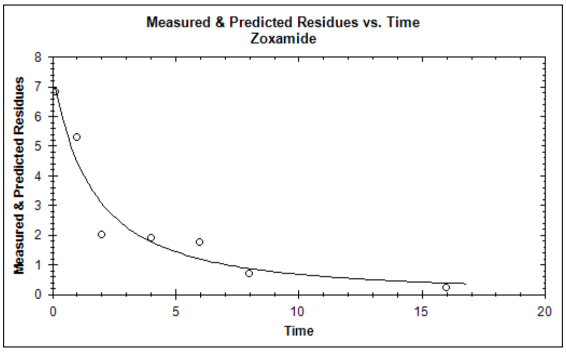
For both crop varieties, the X^2-values for the best fit models are mainly < 15%. Only for sugar beet leaves the first trial yields a X^2-value greater than 15%. Here, the best fit kinetic is FOMC with an error of 18.02 %. However, the visual fit is acceptable and the coefficient of determination (r^2) is equal to 0.94. In general, the coefficients of determination (r^2) for all chosen best fit kinetics is greater than or equal to 0.94. As a result, the correspondence between the model predictions 3and the observed data is good for all data sets. Hence, the calculated DT_{50} values are reliable.

Again, FOMC for sugar beet leaves in trial 2 is clearly identified as best fit. Hockey Stick (HS) is best for the third trial. In this trial, for sugar beet leaves HS is the only fit yielding a X^2-value smaller than 15%.

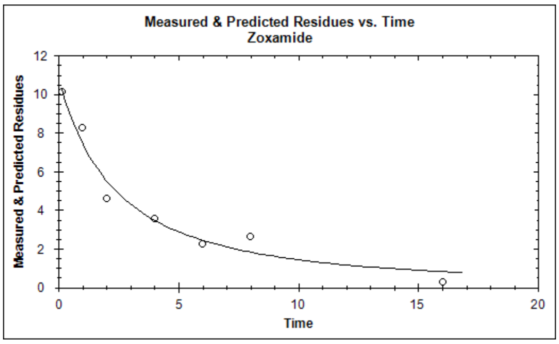
For wheat green mass trial 2 and trial 3 minimum X^2-values were found for SFO kinetics. The choice of kinetics was confirmed by the good visual fits (see following figure, demonstrating good visual fits for the best fit kinetics).

S16-05375-01

sugar beet leaves (FOMC)

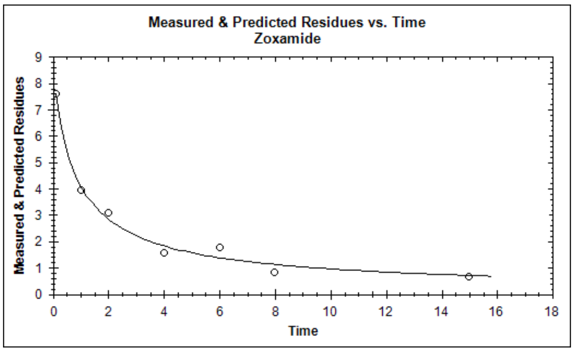


wheat green mass (FOMC)

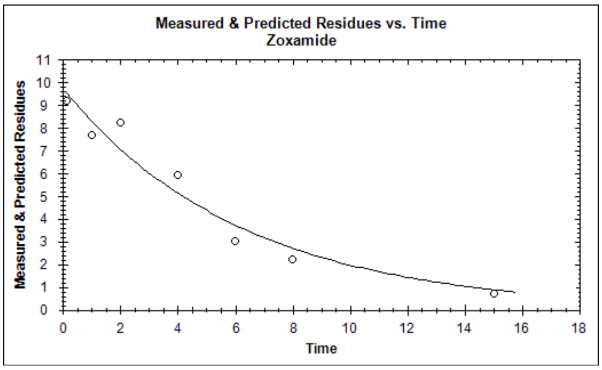


S16-05375-02

sugar beet leaves (FOMC)

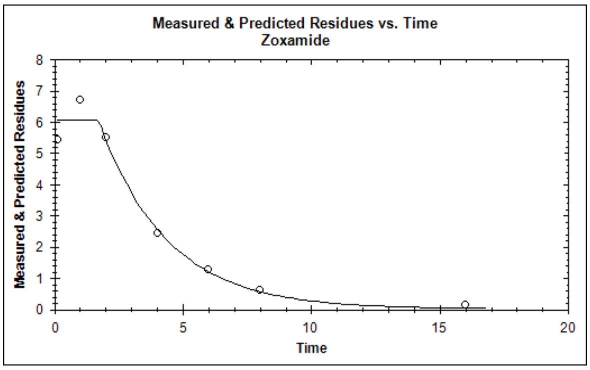


wheat green mass (SFO)



S16-05375-03

sugar beet leaves (HS)



wheat green mass (SFO)

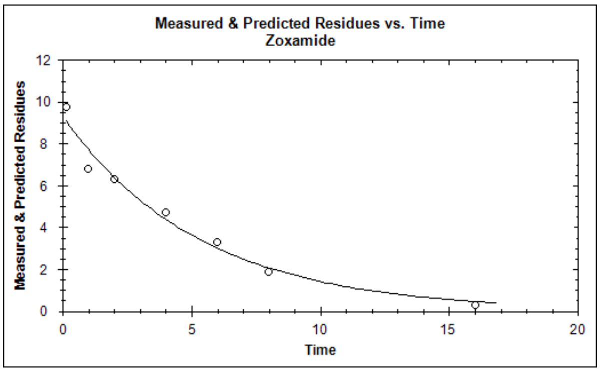


Figure A 10: Plot with the residue decline data of zoxamide using the best fit kinetics for sugar beet leaves and wheat green mass - Northern EU, Study S16-05375

Table A 2-42: Results of calculation for all kinetic models for zoxamide on sugar beet leaves and wheat green mass; Southern EU study S16-05376

	Crop	Field trial no.	Kinetics	X^2 [%]	r^2	DT_{50} [d]	DT_{90} [d]
Southern EU	sugar beet leaves	S16-05376-01	**SFO**	**23.8**	**0.9**	**2.6**	**8.64**
			FOMC	33.21	0.85	1.7	5.64
			DFOP	28.33	0.9	2.6	8.64
			HS	28.33	0.9	2.6	8.64
		S16-05376-02	SFO	10.74	0.94	5.02	16.67
			FOMC	11.98	0.95	5.49	18.25
			DFOP	12.79	0.94	5.02	16.67
			HS	**4.32**	**0.99**	**5.65**	**14.38**
		S16-05376-03	**SFO**	**18.22**	**0.9**	**2.89**	**9.6**
			FOMC	19.68	0.9	2.87	9.55
			DFOP	21.24	0.9	2.74	11.19
			HS	20.45	0.91	2.72	14.91
	wheat green mass	S16-05376-01	**SFO**	**9.83**	**0.98**	**2.35**	**7.8**
			FOMC	11.31	0.98	2.15	7.15
			DFOP	11.7	0.98	2.35	7.8
			HS	9.98	0.99	2.61	7.19
		S16-05376-02	**SFO**	**13.91**	**0.87**	**6.19**	**20.57**
			FOMC	15.59	0.87	5.39	17.93
			DFOP	16.56	0.87	6.19	20.57
			HS	15.84	0.88	6.68	17.98
		S16-05376-03	SFO	10.44	0.88	6.94	23.04
			FOMC	8.76	0.93	5.73	62.53
			DFOP*	**8.76**	**0.94**	**5.32**	**n.a.**
			HS	12.43	0.88	6.99	23.09

For sugar beet leaves, trial 1 and trial 3 follow first-order kinetic (SFO). For SFO the smallest X^2-values are found. However, the X^2-values are greater than 15%. Due to the coefficient of 0.9 and the visual result, the fitting result is acceptable and the resulting DT_{50} values are reliable.

The hockey stick model (HS) is clearly identified as best fit for sugar beet leaves in trial 2, indicated by a very small X^2-value, namely 4.32%.

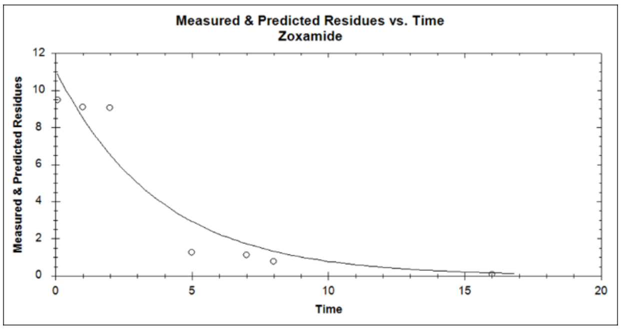
In general, the coefficients of determination (r^2) for all chosen best fit kinetics are greater than or equal to 0.9. As a result, the correspondence between the model predictions and the observed data is good for all data sets. Hence, the calculated DT_{50} values are reliable.

For wheat green mass all chosen best fit models yield X^2-values smaller than 15%, indicating a good correspondence between experimental data and fit. For trial1 and trial 2 SFO is chosen as best fit kinetics. For the third trial, DFOP and FOMC result in a very similar X^2-value, namely 8.76%. In this case, DFOP is selected as best-fit kinetic since the coefficient of determination r^2 is slightly better. Furthermore, the visual result is very acceptable.

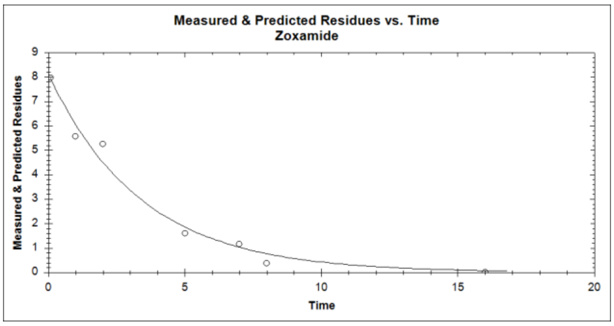
The choice of kinetics was confirmed by the good visual fits (see next figure, demonstrating good visual fits for the best fit kinetics).

S16-05376-01

sugar beet leaves (SFO)

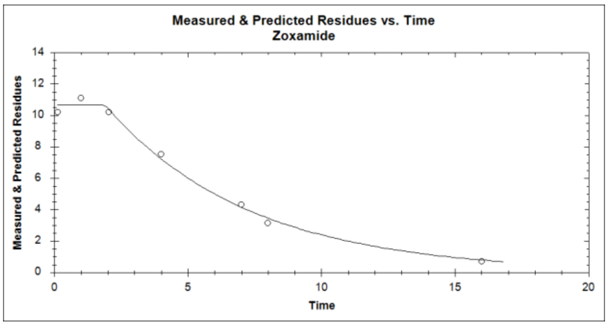


wheat green mass (SFO)

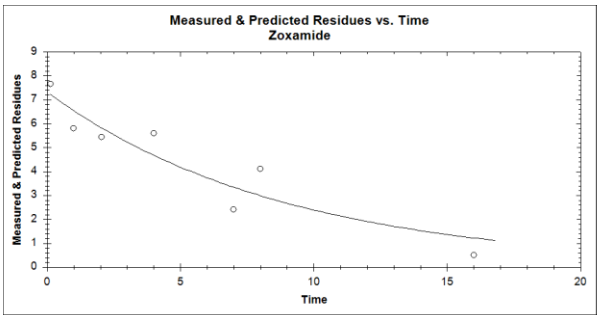


S16-05376-02

sugar beet leaves (HS)

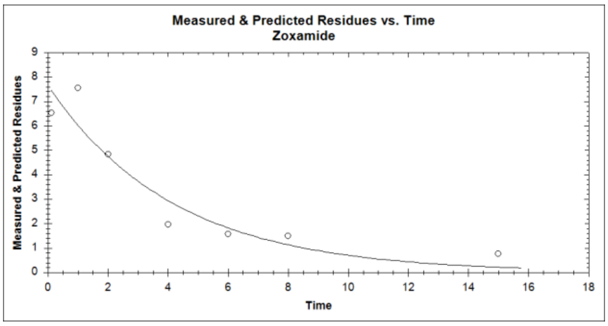


wheat green mass (SFO)



S16-05376-03

sugar beet leaves (SFO)



wheat green mass (DFOP)

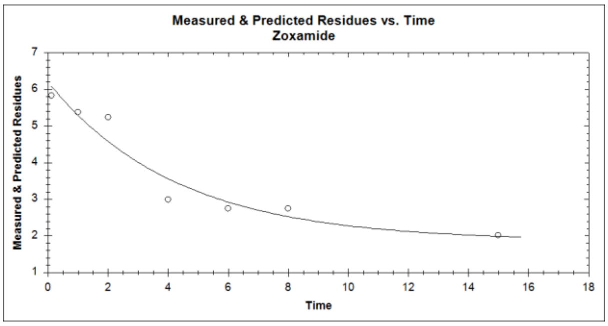


Figure A 11: Plot with the residue decline data of zoxamide using the best fit kinetics for sugar beet leaves and wheat green mass - Southern EU, Study S16-05376 performed by Appeltauer (2020b)

Table A 2-43: Results of calculation for all kinetic models for zoxamide on sugar beet leaves and wheat green mass; Northern EU, study S19-01450

	Crop	Field trial no.	Kinetics	X^2 [%]	r^2	DT_{50} [d]	DT_{90} [d]
Northern EU	sugar beet leaves	S19-01450-01	**SFO**	**5.01**	**0.97**	**10.81**	**35.90**
			FOMC	5.20	0.97	10.33	43.62
			DFOP	5.46	0.97	10.37	38.68
			HS	5.77	0.97	10.96	35.98
	wheat green mass	S19-01450-01	SFO	9	0.96	5.44	18.06
			FOMC	9.06	0.96	5.09	21.32
			DFOP	9.48	0.96	4.99	28.75
			HS	**8.83**	**0.97**	**5.83**	**17.05**

For both crop varieties, the X^2-values for the all-fit models are smaller than 15% and the coefficients of determination (r^2) for all fit kinetics are greater than 0.96.

For sugar beet leaves, the best-fit kinetic with the smallest X^2-value is SFO. Thus, SFO is selected as best-fit kinetic. As a result, the correspondence between the model predictions and the observed data is good for all data sets. Hence, the calculated DT_{50} values are reliable.

For wheat green mass, X^2-values are for all kinetic models in a similar range. The smallest X^2-values is obtained for Hockey Stick (HS) kinetics. The choice of kinetics was confirmed by the good visual fits (see next figure, demonstrating good visual fits for the best fit kinetics).

S19-01450

sugar beet leaves (SFO) wheat green mass (HS)

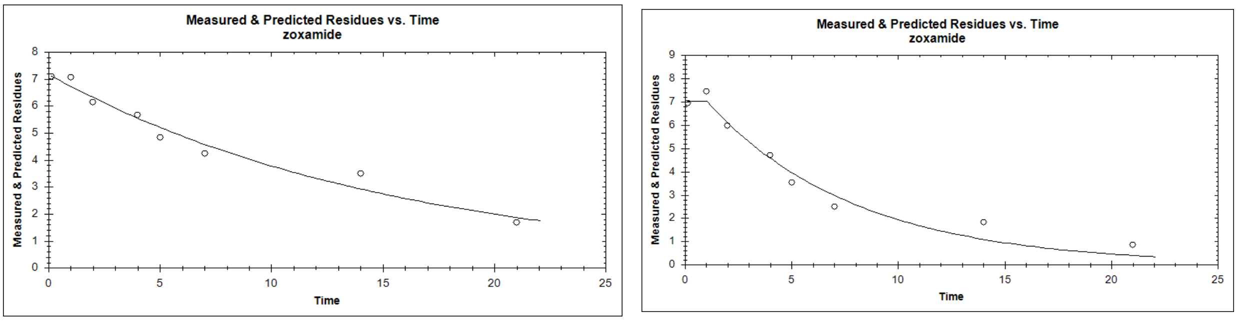


Figure A 12: Plot with the residue decline data of zoxamide using the best fit kinetics for sugar beet leaves and wheat green mass - Northern EU, study S19-01450 performed by Appeltauer (2020c)

Table A 2-44: Zoxamide residues on sugar beet leaves and wheat green mass, study S19-23773; Southern EU, Study S19-23773

	Crop	Field trial no.	Kinetics	X² [%]	r²	DT_{50} [d]	DT_{90} [d]
Southern EU	sugar beet leaves	S19-23773-01	SFO	11.57	0.88	6.86	22.78
			FOMC	10.8	0.91	4.37	111.4
			DFOP	8.76	0.95	3.6	23.73
			HS*	**8.76**	**0.95**	**4.93**	**25.14**
	wheat green mass	S19-23773-01	**SFO**	**5.77**	**0.98**	**4.62**	**15.35**
			FOMC	6.05	0.98	4.38	16.71
			DFOP	6.22	0.99	4.25	16.04
			HS	6.86	0.98	4.62	15.39

* selected based on visual fit since no distinction could be found based on chi² and r² for DFOP and HS. The selection also represent the worst case

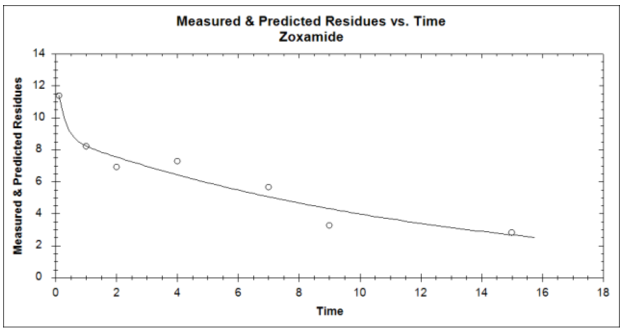
For both crop varieties, the X²-values for the all-fit models are smaller than 15% and the coefficients of determination (r^2) for all fit kinetics are greater than 0.96.

For sugar beet leaves, the smallest X²-values are obtained for DFOP and HS, namely 8.76%. As both, X²-values and coefficient of determination (r²). HS is selected as best fit kinetic as it represents the worst-case.

For wheat green mass, X²-values are for all kinetic models in a similar range. The smallest X²-values is obtained for single first order (SFO) kinetics. The choice of kinetics was confirmed by the good visual fits (see next figure, demonstrating good visual fits for the best-fit kinetics).

S19-01450

sugar beet leaves (DFOP)



wheat green mass (SFO)

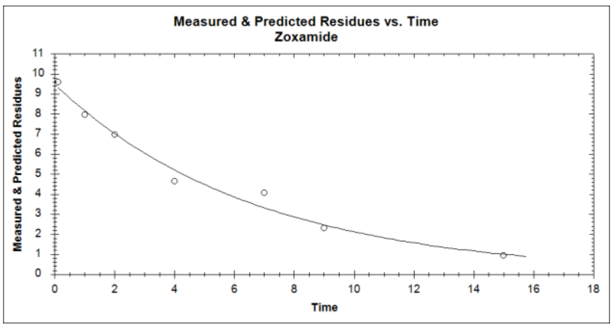


Figure A 13: Plot with the residue decline data of zoxamide using the best fit kinetics for sugar beet leaves and wheat green mass -Northern EU, Study S19-23773 performed by Appeltauer (2020d)

In the kinetic evaluation report the fitting results are presented in more detail.

The overall results are summarised in the following table.

Table A 2-45: Residue dissipation of zoxamide on sugar beet leaves and wheat green mass in Northern and Southern EU

	Field trial no.	Crop	Kinetics	X^2 [%]	r^2	DT_{50} [d]
Northern EU	S16-05375-01	sugar beet leaves	FOMC	18.02	0.94	1.43
	S16-05375-02		FOMC	7.27	0.99	0.86
	S16-05375-03		HS	10.34	0.98	3.55
	S19-01450-01		SFO	5.02	0.97	10.81
	S16-05375-01	wheat green mass	FOMC	11.42	0.97	2.07
	S16-05375-02		SFO	10.22	0.95	4.31
	S16-05375-03		SFO	8.04	0.97	3.65
	S19-01450-01		HS	8.83	0.97	5.83
	Geometric mean half-live (n = 8) Northern EU ± SD					**3.1 ± 3.2**
Southern EU	S16-05376-01	sugar beet leaves	SFO	23.8	0.9	2.6
	S16-05376-02		HS	4.32	0.99	5.65
	S16-05376-03		SFO	18.22	0.9	2.89
	S19-23773-01		HS	8.76	0.95	4.93
	S16-05376-01	wheat green mass	SFO	9.83	0.98	2.35
	S16-05376-02		SFO	13.91	0.87	6.19
	S16-05376-03		DFOP	8.76	0.94	5.32
	S19-23773-01		SFO	5.77	0.98	4.62
	Geometric mean half-live (n = 8) Southern EU ± SD					**4.1 ± 1.5**
	Geometric mean half-live (n = 16) ± SD					**3.6 ± 2.4**

In total 8 trials were performed under each Northern and Southern EU growing conditions. The geometric mean half-life based on the Northern studies is smaller (3.1 days) than the geometric half-life for Southern EU (4.1 days), but therefore shows a greater range than the study results from the South. The overall geometric mean based on both, Northern and Southern EU, is equal to 3.6 days.

Further similar residue decline studies for zoxamide have been analysed previously (Klein et al. 2020). The studies describe the residue behaviour of zoxamide on open headed salad variations (as surrogate plants for leafy crops) under indoor and outdoor (Southern European) conditions:

1. Salad under open field southern EU: Doc. No. 644-007 KCP 9.2.5/04
2. Salad under indoor conditions: Doc. No. 644-008 KCP 9.2.5/05
3.

In order to calculate an overall DT_{50} of all experiments, these studies were included. As presented in the next table, the overall DT_{50} value based on all studies (n = 32) is 3.9 days.

Table A 2-46: Overall geometric mean for the residue dissipation of zoxamide under Southern and Northern EU field and indoor conditions

	Field trial no.	Crop	Kinetics	X² [%]	r²	DT_{50} [d]
Northern EU	S16-05375-01	sugar beet leaves	FOMC	18.02	0.94	1.43
	S16-05375-02		FOMC	7.27	0.99	0.86
	S16-05375-03		HS	10.34	0.98	3.55
	S19-01450-01		SFO	5.02	0.97	10.81
	S16-05375-01	wheat green mass	FOMC	11.42	0.97	2.07
	S16-05375-02		SFO	10.22	0.95	4.31
	S16-05375-03		SFO	8.04	0.97	3.65
	S19-01450-01		HS	8.83	0.97	5.83
	Geometric mean half-live (n = 8) Northern EU ± SD					**3.1 ± 3.2**
Southern EU	S16-05376-01	sugar beet leaves	SFO	23.8	0.9	2.6
	S16-05376-02		HS	4.32	0.99	5.65
	S16-05376-03		SFO	18.22	0.9	2.89
	S19-23773-01		HS	8.76	0.95	4.93
	S16-05376-01	wheat green mass	SFO	9.83	0.98	2.35
	S16-05376-02		SFO	13.91	0.87	6.19
	S16-05376-03		DFOP	8.76	0.94	5.32
	S19-23773-01		SFO	5.77	0.98	4.62
	Geometric mean half-live (n = 8) Southern EU ± SD					**4.1 ± 1.5**
Open field, Southern EU *	RA 12 058BPL IT 01	Lettuce Trocadero (1)	SFO	11.7	0.9452	5.53
		Lettuce Trocadero (2)	SFO	6.79	0.9834	5.22
	RA 12 058BPL IT 02	Lettuce Trocadero (3)	SFO	6.65	0.9864	4.44
		Lettuce Trocadero (4)	HS	6.58	0.9888	1.79
	RA 12 058BPL IT 03	Rocket salad Selvatica (1)	HS	3.63	0.9968	2.34
		Rocket salad Selvatica (2)	HS	3.46	0.9962	5.66
	RA 12 058BPL IT 04	Endive Quintana (1)	SFO	8.14	0.9374	8.53
		Endive Quintana (2)	HS	1.09	0.9989	11.6
	Geometric mean half-live (n = 8) open field, Southern EU ± SD					**4.8 ± 3.2**
Indoor **	R03AG12-01	Lettuce Maximus (1)	FOMC	4.75	0.9974	2.24
		Lettuce Maximus (2)	SFO	21.5	0.9163	3.87
	R03AG12-02	Lettuce Fabietto (1)	HS	2.23	0.9995	2.89
		Lettuce Fabietto (2)	SFO	19.3	0.926	3.92
	R03AG12-03	Rocket salad Broadleaf (1)	SFO	8.94	0.9692	5.22
		Rocket salad Broadleaf (2)	HS	0.0648	1	2.94
	R03AG12 -04	Escarole Arlonia (1)	SFO	22.1	0.9116	3.64
		Escarole Arlonia (2)	SFO	14.8	0.9277	5.15
	Geometric mean half-live (n = 8) Indoor ± SD					**3.6 ± 1.1**
Overall geometric mean half-live (n =32) ± SD						**3.9 ± 2.4**

* Doc. No. 644-007 KCP 9.2.5/04
** Doc. No. 644-008 KCP 9.2.5/05

In summary, DT_{50} values (n=16) for zoxamide on sugar beet leaves and wheat green mass coming from Northern and Southern EU trials is 3.6 days. This value is regarded representative to describe the residue dissipation behaviour of zoxamide on leafy (dicotyledonae) and grass-like (monocotyledonae) plants.

The geometric mean DT_{50} value (n=16) for zoxamide on leafy salad plants grown under indoor and southern European field conditions amounts to 4.2 days. This value is regarded representative to describe the residue dissipation behaviour of zoxamide on leafy (dicotyledonous) plants.

The overall geometric mean DT_{50} value (n=32) for zoxamide on sugar beet leaves (surrogate dicotyledonae plant) and wheat green mass (surrogate monocotyledonae/grass-like plant) performed under northern and southern European growing conditions, including additional study results from open head salad plants (leafy dicotyledonous plants) grown under indoor und Southern European conditions was found to be 3.9 days. This value is regarded representative to describe the substance-specific residue dissipation of zoxamide on/in plants.