

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: Cymoxanil 33% + Zoxamide 33% WG

Product name(s): **Lieto 66 WG**

Chemical active substance(s):

Zoxamide, 330 g/kg

Cymoxanil, 330 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(product re-registration)

Applicant: Sipcam Oxon S.p.A.

Submission date: 30/12/2020

MS Finalisation date: September 2021

Revision date: December 2021

DATA PROTECTIO CLAIM

Under Article 59 of Regulation 1107/2009/EC, the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

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Version history

When	What
30 th December 2020	Submission of initial Version 0 by the applicant
21 st April 2021	Version revised by the applicant, highlighting confirmatory-like studies which are under evaluation by the RMS for Zoxamide in an interzonal procedure.
September 2021	zRMS version
December 2021	Revised version, addressing the comments of MSs.

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate data and modelling on the plant protection product 'Cymoxanil 33% + Zoxamide 33% WG'. The product contains the two active substances cymoxanil and zoxamide, which are both in the Annex of Regulation (EU) 540/2011 (former Annex I of Directive 91/414/EEC). 'Cymoxanil 33% + Zoxamide 33% WG' is an authorised plant protection product in European countries, for which re-registration has been requested under art. 43 of Reg. (EU) 1107/2009 on behalf of the sponsor Gowan Crop Protection Ltd., UK. The dossier follows the data requirements of

- Regulation (EC) No. 544/2011 for the active substance cymoxanil,
- Regulation (EC) No. 283/2013 for the active substance zoxamide and
- Regulation (EC) No. 284/2013 for the plant protection product 'Cymoxanil 33% + Zoxamide 33% WG'.

This document is for the renewal of the authorisation of the product according to Article 43 of Regulation (EC) No 1107/2009, following the renewal of approval of the active substance zoxamide according to Regulation (EU) 2018/1981 of 13 December 2018.

The aim of this step of the art. 43 process is to update the existing dossier information with regard to and limited to the information on the active substance zoxamide as follows:

- To comply with data requirements or criteria which were not in force when the authorisation of the plant protection product was granted and
- to demonstrate that the product meets the requirements set out in the Regulation on the renewal of the approval of the active substance zoxamide to comply with provisions of article 29 of Regulation (EU) No 1107/2009.

This dossier contains the consolidated version of the previous assessment for the parts which do not require a re-evaluation, including all assessments and data on cymoxanil. The consolidated text has been shaded in grey in the present dRR section. Please note that for product authorization the core document in the central zone also included Romania with a tomato use, since Romania at that time belonged to the S-EU zone.

A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product ‘CYMOXANIL 33% + ZOAXAMIDE 33% WG’

[illegible]

- * Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
- ** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

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

Zoxamide

The representative formulation during EU renewal of zoxamide was GWN-9790EU (synonym name “Zoxium 240 SC”), an SC formulation containing 240 g/L zoxamide. During AIR of zoxamide also a use on potatoes and grapes in the central EU zone has been evaluated. However, on EU level a higher number of applications (5 applications) and higher single application rates (180 g a.s./ha) with a greater seasonal application rate (0.9 kg a.s./ha) at a comparable minimum application interval of 8 days and the same phi values were taken into account. The GAP uses defended on EU level can therefore be regarded as worst-case.

Table 8.1-2: Assessed (critical) uses during approval of zoxamide 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, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (d)	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		
13- 16	CEU, SEU	Wine and table grape	F	grape downy mildew <i>Plasmopara viticola</i>	3-d broadcast with mist blower	BBCH 15- 79	a) 5 b) 5	8	a) 0.75 L/ha b) 3.75 L/ha	a) 0.18 kg as/ha b) 0.90 kg as/ha	1000	28	
1-12	NEU, CEU, SEU	Potato	F	potato late blight <i>Phytophthora infestans</i>	broadcast with spray boom	BBCH 20- 80	a) 5 b) 5	8	a) 0.75 L/ha b) 3.75 L/ha	a) 0.18 kg as/ha b) 0.90 kg as/ha	1000	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

Cymoxanil

The representative formulation during EU renewal of cymoxanil were “CYM 50” and “Tanos”, a WP and WG formulation containing 500 g/kg and 250 g/kg respectively. The evaluated representative uses are as a fungicide on lettuce and potato. A maximum of 4 applications, with an application rate of 240 g a.i./ha and 7 days interval were approved on lettuce. A maximum of 5 applications, with an application rate of 120 g a.i./ha and 7 days interval were approved on potato for CYM 50 and a maximum of 8 applications, with an application rate of 175 g a.i./ha and 7 days interval were approved on potato for Tanos.

Table 8.1-3: Assessed (critical) uses during approval of cymoxanil 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 (d)	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		
	SEU	Lettuce	F	<i>Bremia lactucae</i>	Spray	BBCH 40- 49	a) 4 b) 4	7	a) 0.480 kg/ha b) 1.92 kg/ha	a) 0.240 kg as/ha b) 0.960 kg as/ha	500-800	10	
1-12	NEU	Potato	F	<i>Phytophthora infestans</i>	Spray	BBCH 21- 95	a) 4 b) 4	7	a) 0.240 kg/ha b) 0.960 L/ha	a) 0.120 kg as/ha b) 0.480 kg as/ha	200-450	7	
	SEU	Potato	F	<i>Phytophthora infestans</i>	Spray	BBCH 21- 95	a) 5 b) 5	7	a) 0.240 kg/ha b) 0.960 L/ha	a) 0.120 kg as/ha b) 0.480 kg as/ha	500-1000	7	
	NEU, SEU	Potato	F	<i>Phytophthora infestans</i>	Spray	BBCH 21- 95	a) 8 b) 8	7	a) 0.700 kg/ha b) 5.600 kg/ha	a) 0.175 kg as/ha b) 1.400 kg as/ha	300-600	14	

* 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

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

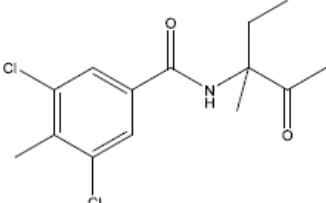
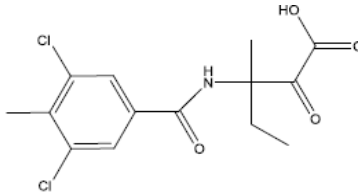
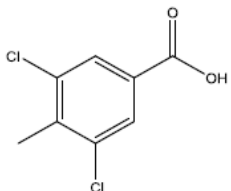
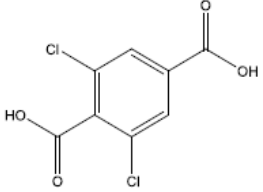
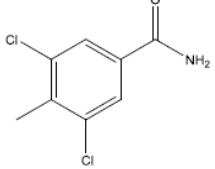
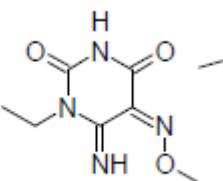
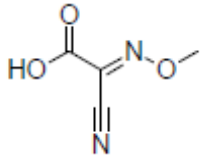
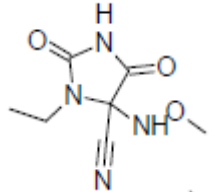
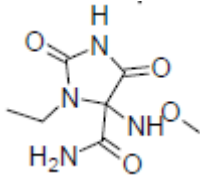
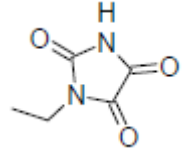
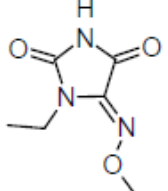
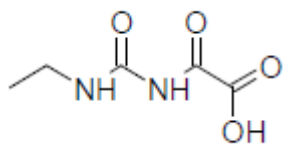
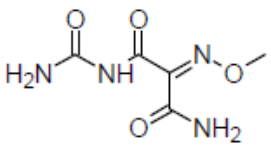
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
RH-127450	302.15		Soil: Max. 15.1% AR after 7 days Water/sediment system: Max. 17.1% AR in surface water (day 28), max. 23.1% AR in sediment, max. 39.3% AR in total system (after incubation at 10°C)	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil 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 _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil 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 _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil 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 _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/sed} : occurrence in surface water
RH-139432	204.06		Soil: Max. 4.9% AR after 14 days Surface water: Max. of 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

Table 8.2-2: Metabolites of cymoxanil potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IN-U3204	198.2		Soil: max 24.7% AR by 0.33 day Water/sediment: max in water 24.7% AR after 0.13 d, max in sediment 0.5% AR after 3 d	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/soil} : occurrence in surface water
IN-W3595	128.1		Soil: max 10.1% AR by 1 day Water/sediment: max in water 26.1% AR after 0.25 d, max in sediment 2.3% AR after 1 d	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/soil} : occurrence in surface water
IN-JX915	198.2		Soil: 10.9% AR (n=1) Water/sediment: max in water 7.2% AR after 1 d, max in sediment 1.2% AR after 1 d	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/soil} : occurrence in surface water
IN-KQ960	216.9		Groundwater: max 6.3% AR by 3 days Water/sediment: max in water 13.0% AR after 1 d, max in sediment 5.5% AR after 30 d	PEC _{gw} : leaching potential to groundwater PEC _{sw/soil} : occurrence in surface water
IN-TA226	142.1		Water/sediment: max in water 11.1% AR after 3 d, max in sediment 1.0% AR after 8 d	PEC _{sw/soil} : occurrence in surface water
IN-R3273	171.2		Water/sediment: max in water 5.0% AR after 3 d, max in sediment 0.5% AR after 3 d	PEC _{sw/soil} : occurrence in surface water
IN-KP533	160.1		Water/sediment: max in water 20.5% AR after 10 d, max in sediment 6.5% AR after 1 d	PEC _{sw/soil} : occurrence in surface water
M5	198.2		Water/sediment: max in water 22.9% AR after 1 d, max in sediment 0.0% AR	PEC _{sw/soil} : occurrence in surface water

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.

Zoxamide

The fate and behaviour of zoxamide in soil is discussed in detail in the corresponding document of the EU review dossier (RAR 2017) and the EFSA Peer Review Conclusion (2017).

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 especially formation fraction (ff) values for its transformation product RH-141455 in three different soils under aerobic conditions in the dark.

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

Cymoxanil

The fate and behaviour of cymoxanil in soil is discussed in detail in the corresponding document of the EU review dossier (DAR 2007) and the EFSA Peer Review Conclusion (2008).

However, to refine the groundwater risk assessment for metabolite IN-KQ960, further data has been generated (Clark, 2010a, ref. KCP 9.1.1/01).

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

The type of formulation used in 'Cymoxanil 33% + Zoxamide 33% WG' is not expected to affect the rate of degradation in soil and data generated with the unformulated material are considered to be applicable to the formulation. Therefore, 'Cymoxanil 33% + Zoxamide 33% WG' was not tested for rate of degradation in soil under laboratory conditions.

8.3.1.1 Zoxamide and its metabolites

Please refer to the information provided in the RAR (2017) and the EFSA Peer Review Conclusion (2017).

Degradation of zoxamide (code RH-7281) 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 degradates 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 CO₂ 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 taken into account. It develops from the metabolite RH-24549.

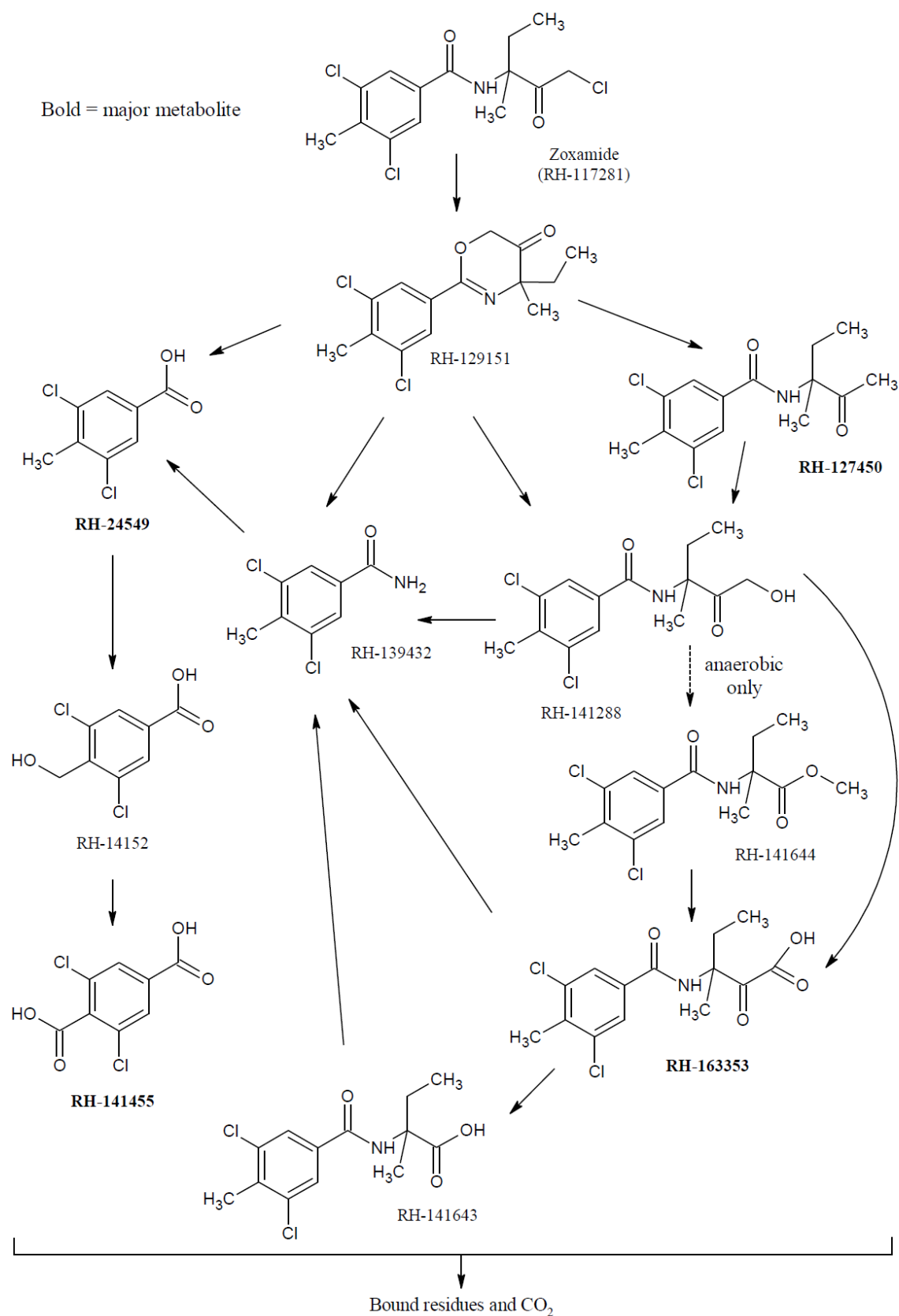


Table 8.3-1: Summary of aerobic degradation rates for zoxamide - laboratory studies

EFSA (2017)¹ set an (unrealistic) 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 (Burgener, 1998; see 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. Therefore, a new soil degradation study has been performed with [¹⁴C]-RH-24549 (Derz, 2020) 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. 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 Peer Review Conclusion (2017). A summary of the report of Klein & Mendel-Kreusel (2020) can be found in Appendix 2, a summary of the overall results for RH-24549 and RH-141455 in Table 8.3-4 and Table 8.3-6, respectively.

DT₅₀ values for zoxamide and its metabolites are given in the tables below. Geometric mean modelling DT₅₀ values were calculated for soils incubated at 20/25°C. Where a number of DT₅₀ values were obtained from the same soil (e.g. German sandy loam), only the DT₅₀ 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 8.3-2: 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	Chi ² (%)	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 (EFSA, 2017)
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 ¹	4.65	SFO	
			20	100% FC	2.22	7.38	2.22	6.72	SFO	
			10	50	7.29	24.2	2.81 ¹	6.78	SFO	
Pennsylvania, USA	silt loam	6.8	25	75% FC	29.5 ²	--	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 (modelling)	
					13.6	115	--		DFOP (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

^o EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zox-amide. EFSA Journal 2017, 5 (9):4980

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

² DT₉₀/3.32

The geometric mean DegT₅₀ of 5.5 days (n=6) for zoxamide in soil was used for surface- and groundwater simulations. For PEC_{soil} calculations the slow-phase DT₅₀ 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 8.3-3: 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 ^o
Shelly, England	silt loam	5.0	20	50	14.9	49.5	12.52	9.61	SFO-SFO	y (EFSA, 2017)
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 ¹	19.3	SFO-SFO	
			20	100% FC	5.79	19.2	5.79	23.9	SFO-SFO	
			10	50	18.7	62	7.22 ¹	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			

^o EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zox-amide. EFSA Journal 2017, 5 (9):4980

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

For RH-127450 the geometric mean DegT₅₀ of 5.2 days (n=5) was used for surface- water and groundwater simulations. Besides an arithmetic mean formation fraction (ff) of 0.24 (n=5) from the parent compound zoxamide (please refer to EFSA, 2017²). For PEC_{soil} the worst-case half-life at 20 °C of 14.9 days was considered for the calculations.

² EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9):4980

Table 8.3-4: 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 (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	n (Derz, 2020)
RefeSol 01-A	sandy loam	5.7	20	45	11	24.6	8.52	2.22	HS	
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)

⁰ EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9):4980

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

Bold = value taken forward for the PEC calculation.

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 DegT₅₀ of 6.84 days (n=7) was used for surface- and groundwater simulations. Besides an arithmetic mean formation fraction (ff) of 0.38 (n=4) from the parent compound zoxamide (please refer to EFSA, 2017³). For PEC_{soil} calculations the worst-case half-life of 13.8 days was considered.

Evaluator's Comments:	<p>RMS for zoxamide evaluates the study for interzonal endpoints change (DT₅₀ for metabolites RH-24549 and RH-141455).</p> <p>The new study was conditionally accepted.</p> <p>These values will be used in further exposure assessment.</p> <p>The final decision to use the recalculated endpoint will be made at Member State level.</p>
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³ EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9):4980

Table 8.3-5: 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 (EFSA, 2017)	
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 ¹	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				

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

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

Bold = value taken forward for the PEC calculation.

For RH-163353 a geometric mean DegT₅₀ of 10.8 days (n=4) was used for surface- and groundwater simulations. Besides an arithmetic mean formation fraction (ff) of 0.18 (n=4) from the parent compound zoxamide (please refer to EFSA, 2017⁴). For PEC_{soil} the worst-case half-life of 49.7 days was considered for the calculations.

⁴ EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9):4980

Table 8.3-6: 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	Evaluate d 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 (Derz, 2020)
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 DT₅₀ mainly due to low detections

² study conducted with RH-141455

³ study conducted with RH-24549 as precursor of RH-141455

Bold = value taken forward for the PEC calculation.

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 0.504 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 [¹⁴C]-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 DegT₅₀ value of 7.48 days (n=7). The geometric mean DegT₅₀ of 7.48 days (n=7) and the arithmetic mean formation fraction (ff) of 0.504 (n=4) was used for surface- and groundwater simulations. For PEC_{soil} calculations the worst-case half-life of 88.5 days was considered.

The DT₅₀ 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), a summary of the evaluation can be found in Appendix 2 of this report.

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) 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.*

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

Evaluator's Comments:	RMS for zoxamide evaluates the study for interzonal endpoints change (DT ₅₀ for metabolites RH-24549 and RH-141455). The new study was conditionally accepted and the new values will be used in further exposure assessment. The final decision to use the recalculated endpoints will be made at Member State level.
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8.3.1.2 Cymoxanil and its metabolites

Please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008).

For a summary of the data used for PEC calculations, please refer to Table 8.3-7. Additional data was not required as a result of the review. However, to refine the groundwater risk assessment, further data on the metabolite IN-KQ960 has been generated and is presented in the following.

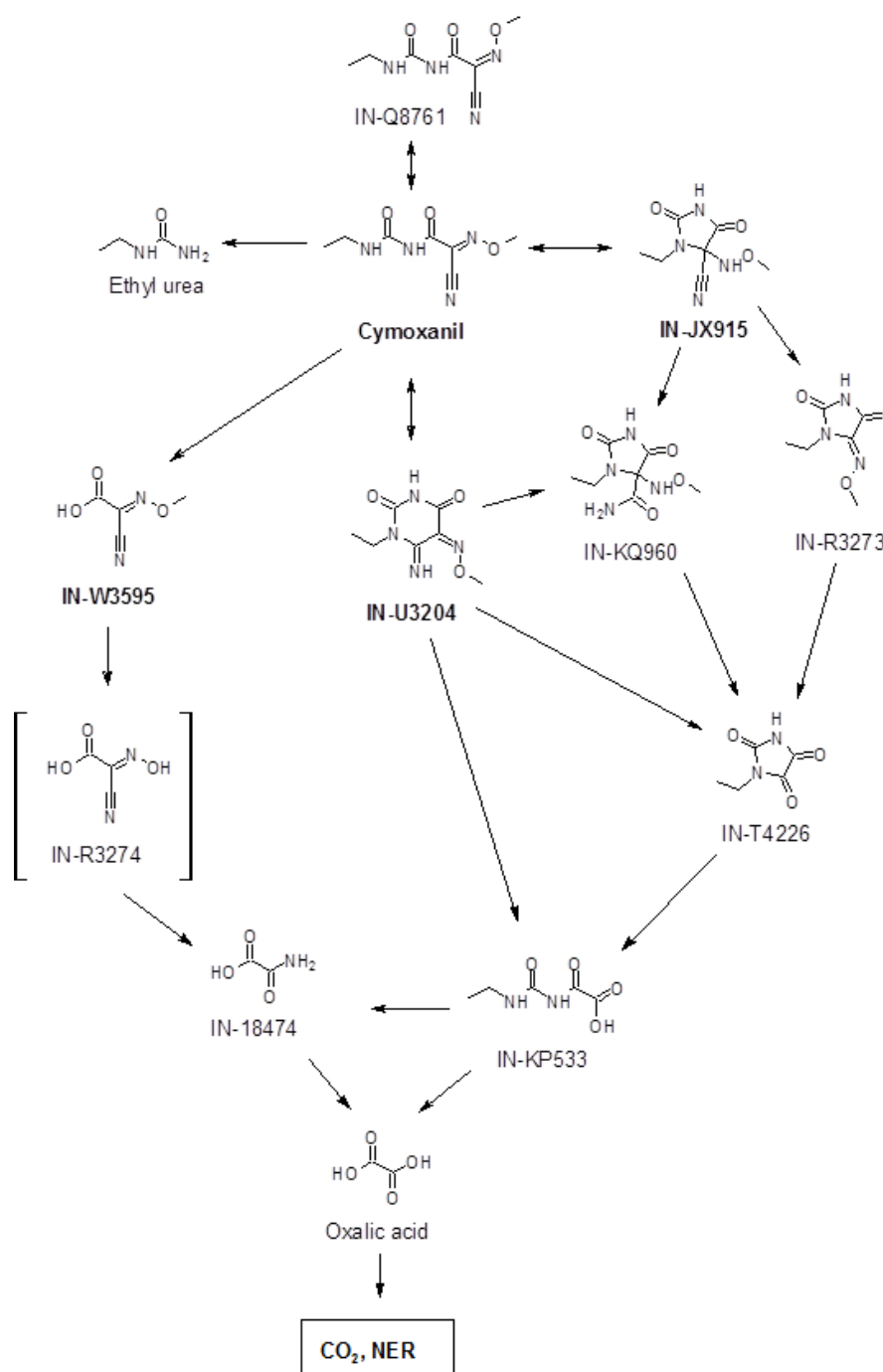


Figure 8.3-1: Proposed pathway of cymoxanil in soil

Table 8.3-7: **Summary of aerobic degradation rates for cymoxanil - laboratory studies**

Cymoxanil, Laboratory studies, aerobic conditions								
Soil type	pH	t.°C/ MWHC %	DT ₅₀ / DT ₉₀ (d)	SFO-DT50 (d) 20 °C pF2/10kPa	r ²	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Sandy loam, UK	6.0	20°C / 40% MWHC	0.1/0.5	0.2	1.00	1.4	FOMC	Yes, LoEP (2008)
Sandy loam, US	6.4	25°C / 75% 1/3 bar	1.2/18.8	5.8	0.86	176	FOMC	
Sandy clay loam, J	6.8	25°C / 50% MWHC	0.2/0.8	0.4	0.98	5.9	FOMC	
Sandy loam, DE	6.5	20°C / 50% MWHC	2.3/13.1	3.1	0.99	6.9	FOMC	
Sandy loam, F	7.8	20°C / 50% MWHC	0.7/2.3	0.6	0.95	16.7	FOMC	
Sandy clay loam, UK	5.7	20°C / 50% MWHC	2.5/33.3	7.3	0.98	6.5	FOMC	
Silt loam, UK	4.3	20°C / 40% MWHC	4.3/23.7	6.1	0.97	4.3	FOMC	
Silt loam, UK	6.4	20°C / 40% MWHC	0.3/3.1	0.8	1.00	2.6	SFO	
Clay loam, UK	7.5	20°C / 40% MWHC	0.2/0.8	0.2	0.99	5.7	SFO	
Geometric mean (n=3)				2.1 1.2				
pH-dependency: y/n					no			

Evaluator's Comments:	The correct endpoint value of DT ₅₀ for cymoxanil based EFSA, 2008 should be 1.2 d not 2.1 d (typo error).
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Table 8.3-8: Summary of aerobic degradation rates for IN U3204 - laboratory studies

Cymoxanil, Laboratory studies, aerobic conditions									
Soil type	pH	t.°C/ MWHC %	DT ₅₀ / DT ₉₀ (d)	f.f. (from the parent)	SFO- DT50 (d) 20 °C pF2/10kPa	r ²	Chi2 (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy clay loam, J	6.8	25°C / 50% MWHC	0.6/1.9	0.48	0.9	0.93	11.0	P _{SFO} → M _{SFO}	Yes, LoEP (2008)
Sandy loam, UK	6.4	20°C / 40% MWHC	0.4/1.3	0.24	0.3	0.88	26.2	P _{SFO} → M _{SFO}	
Clay loam, UK	7.5	20°C / 40% MWHC	0.2/0.6	0.36	0.2	0.95	12.2	P _{SFO} → M _{SFO}	
Geometric mean (n=3)			0.4/1.1		0.4				
Arithmetic mean (n = 3)			-	0.36					
pH-dependency: y/n						no			

Table 8.3-9: Summary of aerobic degradation rates for IN W3595 - laboratory studies

Cymoxanil, Laboratory studies, aerobic conditions									
Soil type	pH	t.°C/ MWHC %	DT ₅₀ / DT ₉₀ (d)	f.f. (from the parent)	SFO- DT50 (d) 20 °C pF2/10kPa	r ²	Chi2 (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy clay loam, J	6.8	25°C / 50% MWHC	1.7/5.5	0.15	2.5	0.85	14.5	P _{SFO} → M _{SFO}	Yes, LoEP (2008)
Sandy loam, F	7.8	20°C / 50% MWHC	2.8/9.4	0.07	2.5	0.60	69.3	P _{SFO} → M _{SFO}	
Worst case			2.8/9.4	0.15	2.5				
pH-dependency: y/n						no			

Table 8.3-10: Summary of aerobic degradation rates for IN JX915 - laboratory studies

Cymoxanil, Laboratory studies, aerobic conditions									
Soil type	pH	t.°C/ MWHC %	DT ₅₀ / DT ₉₀ (d)	f.f. (from the parent)	SFO- DT50 (d) 20 °C pF2/10kPa	r ²	Chi2 (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy clay loam, J	6.8	25°C / 50% MWHC	0.6/1.9	0.10	1.0	0.73	27	P _{SFO} → M _{SFO}	Yes, LoEP (2008)
pH-dependency: y/n						no			

Table 8.3-11: Summary of aerobic degradation rates for IN KQ960 - laboratory studies

Cymoxanil, Laboratory studies, aerobic conditions									
Soil type	pH	t.°C/ MWHC %	DT ₅₀ / DT ₉₀ (d)	f.f. (from the parent)	SFO- DT50 (d) 20 °C pF2/10kPa	r ²	Chi2 (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy clay loam, J	6.8	25°C / 50% MWHC	7.6/25.5	0.16	11.2 1	0.84	19.2	P _{SFO} → M1 _{SFO} → M2 _{SFO}	Yes, LoEP (2008)
Sand, Speyer 2.2	6.0	20°C / 8.1% 1/3 bar	-	-	2.6/8.8		0.997	SFO	
Silty clay, Tama	6.4	20°C / 31.1% 1/3 bar	-	-	2.0/6.6		0.995	SFO	No, new study
Clay loam, Lleida	7.7	20°C / 26.5% 1/3 bar	-	-	4.2/14		0.997	SFO	
Sandy loam, Nambshheim	7.4	20°C / 12.6% 1/3 bar	-	-	3.5/11.7		0.989	SFO	
Sandy loam, Sassafras	4.9	20°C / 10.4% 1/3 bar	-	-	2.1/7.1		0.991	SFO	
Geometric mean (n=3)					2.76/9.2*				

pH-dependency: y/n	no
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* The RMS has checked that the correct DT₅₀ values have been taken from the EFSA LoEP and is unsure why the metabolites have been corrected to Q10=2.58 and cymoxanil has not. The RMS does not agree with the proposed geomean DT₅₀ for IN-KQ960 as this value ignores the EFSA LoEP DT₅₀ of 11.2 days; The DT₅₀ can be recalculated using both EFSA agreed endpoints and new DT50 values (subject to validation**), but cannot simply be replaced.

RMS calculates; 11.2, 2.6; 2.0; 4.2; 3.5; 2.1. Geometric mean: **3.49**

**The report “KIIIA 9.1.1/01, Clark B., 2010a: C-IN-KQ960: Rate of Degradation in Five Soils” has been validated and the new DT50 values validated using model maker.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

As it is possible to extrapolate from data provided for the active substance, no further data are provided on the preparation.

Zoxamide

Please refer to the information provided in the RAR (2017) and the EFSA Peer Review Conclusion (2017).

In an anaerobic environment, mineralisation of zoxamide is far less with < 0.1% AR. Non-extractable soil residues amounted to 26.4% AR on day 120, levels of organic volatiles were also <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). However, the possibility that anaerobic conditions are encountered after application of zoxamide to the intended crops is unlikely; the proposed applications in the field will occur during spring and summer. This was agreed by the RMS (please refer to RAR, 2017) and EFSA (2017) for the representative uses on potatoes and vines.

Cymoxanil

Please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008)⁵.

8.4 Field studies (KCP 9.1.1.2)

As it is possible to extrapolate from data provided for both active substances, no further data are provided on the formulation. For zoxamide, please refer to the information in the RAR (2017) and the EFSA Peer Review Conclusion (2017). For cymoxanil, please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008). For cymoxanil, please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008).

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

8.4.1.1 Zoxamide and its metabolites

No studies required since DT₅₀ values from laboratory studies are < 60 days for zoxamide and its metabolites. Therefore, endpoints from field soil dissipation studies are not available.

⁵ EFSA (2008): Conclusion regarding the peer review of the pesticide risk assessment of the active substance cymoxanil. Scientific Report 167, 17 September 2008

8.4.1.2 Cymoxanil and its metabolites

No studies required since DT₅₀ values from laboratory studies are < 60 days for cymoxanil and its metabolites.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation studies are required when DT_{50 lab} > 60 days or DT_{90 field} is greater than one year and when repeated application is envisaged.

Zoxamide

For zoxamide and its metabolites soil accumulation testing is not required since their DT_{50 lab} values are below 60 days. Besides, the DT₉₀ values from laboratory studies are << 365 days for zoxamide and its metabolites. Therefore, the risk of accumulation in soil is negligible, and soil accumulation and plateau concentrations are not required.

Cymoxanil

For cymoxanil and its metabolites soil accumulation testing is not required since their DT_{50 lab} values are below 60 days. Besides, the DT₉₀ values from laboratory studies are << 365 days for cymoxanil and its metabolites. Therefore, the risk of accumulation in soil is negligible, and soil accumulation and plateau concentrations are not required.

8.5 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.

For data on the active substance zoxamide and its metabolites, please refer to the information provided in the RAR (2017) and the EFSA Peer Review Conclusion (2017)⁶. For data on the active substance cymoxanil and its metabolites, please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008)⁷.

8.5.1 Zoxamide and its metabolites

The following information is available on EU level and was used for PEC calculations:

Table 8.5-1: Summary of soil adsorption/desorption for zoxamide

Zoxamide							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (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 (EFSA, 2017)
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	

⁶ EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9):4980

⁷ EFSA (2008): Conclusion regarding the peer review of the pesticide risk assessment of the active substance cymoxanil. Scientific Report 167, 17 September 2008

Zoxamide							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference ^o
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		

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

Bold = value taken forward for the PEC calculation.

In addition to the adsorption/desorption characteristics given above for the parent compound zoxamide, an arithmetic mean K_{om} of 700 L/kg and a geometric mean of 684 L/kg (n=4) were concluded by EFSA (2017)⁸. The geometric mean K_{foc} of 1179 L/kg (n=4) was used for PEC surface- and groundwater calculations.

Table 8.5-2: Summary of soil adsorption/desorption for RH-127450

RH-127450							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference ^o
Borstel, Germany	loamy sand	1.05	6.1	12.14	1156	0.519	y (EFSA, 2017)
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*	
pH-dependency					n		

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

* no reliable value could be achieved, therefore a 1/n value of 0.9 was considered appropriate for modelling

Bold = value taken forward for the PEC calculation.

In addition to the adsorption/desorption characteristics given above for the metabolite RH-127450, an arithmetic mean K_{om} of 388 L/kg and a geometric mean of 344 L/kg (n=3) were concluded by EFSA (2017). For ground- and surface water simulations the geometric mean K_{foc} of 593 L/kg (n=3) was used. The experimentally determined 1/n values were considered to be not reliable, therefore a value of 0.9 was taken into account for modelling.

Table 8.5-3: Summary of soil adsorption/desorption for RH-24549

RH-24549							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference ^o
Iowa/USA	sandy loam	1.3	5.2	4.0	307.43	0.791	y (EFSA, 2017)
Illinois/USA	silty clay loam	2.4	7.3	3.6	150.16	0.833	

⁸ EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9):4980

RH-24549							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference°
Ohio/USA	silt loam	2.0	7.6	1.8	90.55*	0.811	
Arithmetic mean / geometric mean (n=3)					183 / 161	0.811	
pH-dependency					y		

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

* adsorption of RH-24549 is pH dependent, therefore the worst-case Kfoc is considered appropriate for modelling

Bold = value taken forward for the PEC calculation.

For ground- and surface water simulations a worst-case K_{foc} of 90.55 L/kg was taken into account, together with the related 1/n of 0.811.

Table 8.5-4: Summary of soil adsorption/desorption for RH-163353

RH-163353							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference°
Borstel, Germany	loamy sand	1.22	6.1	0.6	50*	1.0*	y (EFSA, 2017)
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		

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

*Koc derived from a Kd of a screening study, therefore a default 1/n value of 1.0 is assumed

Bold = value taken forward for the PEC calculation.

In addition to the adsorption/desorption characteristics given above for the metabolite RH-163353, an arithmetic and geometric mean K_{om} of 39 L/kg (n=3) was concluded by EFSA (2017). For PEC surface- and groundwater calculations the geometric mean K_{foc} of 67 L/kg (n=3) together with the related 1/n of 0.892 (n=3) was used.

Table 8.5-5: Summary of soil adsorption/desorption for RH-141455

RH-141455							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference°
Speyer 2.2	loamy sand	1.87	5.5	0.06	3.1*	1.0*	y (EFSA, 2017)
Speyer 2.3	sandy loam	0.94	6.8	0.03	3.3*	1.0*	
Speyer 6S	clay	1.64	7.1	0.03	2.1*	1.0*	
Arithmetic mean (n=3) / geometric mean (n=3)					2.8 / 2.8	1.0*	
pH-dependency					n		

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

* Koc derived from a Kd from a screening study, therefore a default 1/n value of 1.0 is assumed for modelling

Bold = value taken forward for the PEC calculation.

In addition to the adsorption/desorption characteristics given above for the metabolite RH-141455, an arithmetic and geometric mean mean K_{om} of 1.6 L/kg (n=3) was concluded by EFSA (2017). For surface- and groundwater simulations a geometric mean K_{foc} of 2.8 L/kg was used. 1/n values were not measured in the available OECD 106 screening study, therefore a worst-case default value of 1.0 was set for modelling.

8.5.2 Cymoxanil and its metabolites

Table 8.5-6: Agreed EU endpoints of cymoxanil used in the evaluation

Cymoxanil						
Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level Reference
Silt loam, DE	0.59	6.9	0.090	15.1	0.88	Cymoxanil EFSA Concl. (2008)
Sandy loam, US	1.0	5.7	0.910	87.1	0.87	
Loamy sand, UK	1.6	8.1	0.462	28.9	0.81	
Clay, UK	2.0	7.2	0.856	43.4	0.87	
Arithmetic mean (n=4)				43.6	0.86	
pH-dependency				no		

Table 8.5-7: Agreed EU endpoints of IN W3595 used in the evaluation

Cymoxanil						
Soil type	OC (%)	pH (-)	Kd (mL/g)	Koc (mL/g)	1/n (-)	Evaluated on EU level Reference
Loamy sand, US	2.3	4.6/uk	0.63	27.4	-	Cymoxanil EFSA Concl. (2008)
Sandy loam, US	0.99	7.6/uk	0.026	2.6	-	
Silt loam, US	3.2	7.8/uk	0.074	2.3	-	
Sandy loam, US	0.46	6.4/uk	0.020	4.3	-	
Arithmetic mean (n=4)				9.2	1.0*	
Koc acid Koc base pKa		- 5.2		33.3 2.3 -		
pH-dependency						

* PRAPeR 32 agreed default value

Table 8.5-8: Agreed EU endpoints of IN R3273 used in the evaluation

Cymoxanil						
Soil type	OC (%)	pH (-)	Kd (mL/g)	Koc (mL/g)	1/n (-)	Evaluated on EU level Reference
Loamy sand, US	2.3	4.6/uk	0.59	25.7	-	Cymoxanil EFSA Concl. (2008)
Sandy loam, US	0.99	7.6/uk	0.49	49.5	-	
Silt loam, US	3.2	7.8/uk	1.5	46.9	-	
Sandy loam, US	0.46	6.4/uk	0.21	45.7	-	
Arithmetic mean (n=4)				42	1.0*	
		pH-dependency	yes			

* PRAPeR 32 agreed default value

Table 8.5-9: Agreed EU endpoints of IN JX915 used in the evaluation

Cymoxanil						
Soil type	OC (%)	pH (-)	Kd (mL/g)	Koc (mL/g)	1/n (-)	Evaluated on EU level Reference
Loamy sand, US	2.3	4.6/uk	0.13	5.4	-	Cymoxanil EFSA Concl. (2008)
Sandy loam, US	0.99	7.6/uk	0.34	34.3	-	
Silt loam, US	3.2	7.8/uk	0.66	20.6	-	
Sandy loam, US	0.46	6.4/uk	0.021	4.4	-	
Arithmetic mean (n=4)				16.2	1.0*	
		pH-dependency	no			

* PRAPeR 32 agreed default value

Table 8.5-10: Agreed EU endpoints of IN U3204, IN KQ960 and IN T4226 used in the evaluation

Cymoxanil							
Metabolite	Soil type	OC (%)	pH (-)	Kd (mL/g)	Koc (mL/g)	1/n (-)	Evaluated on EU level Reference
IN U3204	HPLC method	-	-	-	<div>21.6</div> 27.9	1.0*	Cymoxanil EFSA Concl. (2008)
IN KQ960	HPLC method	-	-	-	<div>17.7</div> 21.6	1.0*	
IN T4226	HPLC method	-	-	-	<div>12.9</div> 17.7	1.0*	
IN-KP533		-	-	-	12.9	1.0*	
		pH-dependency		Not applicable			

* PRAPeR 32 agreed default value

Additional data was not required as a result of the review, however to refine risk assessment endpoints for Cymoxanil metabolite IN-KQ960, further data has been generated (Clark, 2010b).

Evaluator's Comments:	The K _{foc} values for metabolites were corrected in accordance with EFSA, 2008. The metabolite IN-KP533 was added.
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Table 8.5-11: K_{oc} and 1/n (Freundlich exponent) values for IN-KQ960 obtained from study 65144 (Clark, 2010b)

End-Point	IN-KQ960
K _{oc}	5.13 ^{A)}
1/n	0.97 ^{A)}

^A geometric mean

8.5.3 Column leaching (KCP 9.1.2.1)

Zoxamide

As outlined above (please refer to chapter 8.5.1), reliable adsorption coefficient values are available for zoxamide and its metabolites. Therefore, the submission of data or information on column leaching of these compounds or the preparation is considered to be no required.

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.

Cymoxanil

Please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008). Since reliable information was found for adsorption/desorption of cymoxanil and its metabolites, column leaching of these compounds is considered to be no required.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Zoxamide

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

Cymoxanil

A lysimeter study on cymoxanil was performed in Germany. Please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008).

8.5.5 Field leaching studies (KCP 9.1.2.3)

Zoxamide

No lysimeter or field leaching studies have been conducted. The leaching behaviour of zoxamide and its

metabolites is adequately assessed using mathematical modelling.

Cymoxanil

No field leaching studies have been conducted. Please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008).

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

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

For data on the active substance zoxamide and its metabolites, please refer to the information provided in the RAR (2017) and the EFSA Peer Review Conclusion (2017)⁹. For data on the active substance cymoxanil and its metabolites, please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008)¹⁰. For data on the active substance cymoxanil and its metabolites, please refer to the information provided in the DAR (2007) and the EFSA Peer Review Conclusion (2008)¹¹.

8.6.1 Zoxamide and its metabolites

In natural waters, the major dissipation routes of zoxamide are hydrolysis, microbial degradation and partitioning to sediment; photolysis plays a minor role.

The parent compound degrades hydrolytically with a DT₅₀ of 16 days (1st order, $r^2 = 1.0$) at pH 7 and 25°C, the metabolite RH-129151 with a DT₅₀ of 9.1 days. Besides, the metabolite RH-150721 was detected at a max. of 1.5% AR at pH 7 on day 30. The metabolites RH-24549 and RH 141288 occurred at amounts of 20.75 and 21.9% AR on day 30 during the laboratory experiment with the parent compound. The metabolites RH-24549 and RH-141288 are hydrolytically stable at pH 7 and 25°C.

At pH 4 and under light (equivalent to light intensity of New Jersey summer sunlight, 42° N), zoxamide degraded with a DT₅₀ of 8 days (12-hour photo-period) and 22 days in dark control (1st order, $r^2 = 0.99 - 1.0$). The metabolites RH-24549 (max. 27.69% AR, day 30), RH-150721 (max. 15.10% AR, day 10) & RH-139432 (max. 42.4% AR, day 30) occurred at levels > 10% AR - but not as photoproducts, since similar levels were measured in dark control samples. However, 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) the degradation of zoxamide was examined in surface water (pelagic test) according to OECD guideline 309. As a result, the parent compound metabolised rapidly with a DT₅₀ of 7.6 to 8.4 days at 20°C and a pH of 7.1-8.4. RH-141455, RH-139432, RH-141288, RH-163353, and RH-24549 were detected at maximum amounts of ≥ 10%.

Table 8.6-1: Summary of observed metabolites of zoxamide – aerobic mineralisation in surface water

RH-141455	Max. in surface water at 10.5% AR (day 44)	
RH-139432	Max. in surface water at 21.4% AR (day 28)	

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

¹⁰ EFSA (2008): Conclusion regarding the peer review of the pesticide risk assessment of the active substance cymoxanil. Scientific Report 167, 17 September 2008

¹¹ EFSA (2008): Conclusion regarding the peer review of the pesticide risk assessment of the active substance cymoxanil. Scientific Report 167, 17 September 2008

RH-141288	Max. in surface water at 22.1% AR (day 58)	Evaluated on EU level: y EFSA (2017) ^o
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.	

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

Table 8.6-2: 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 ^o
High dose	SFO / 20°C	7.6	25.4	12.1	Y	y EFSA (2017)
	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	

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

¹ Q₁₀ used for normalisation = 2.58 days

The decline of zoxamide and its metabolite RH-127450 was studied in water water/sediment systems incubated at 10 and 20°C. As a result, 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, respectively, and then declined. At 20°C this metabolite 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 this metabolite, a formation fraction (ff) of 0.24 - 0.33 from parent compound was concluded by EFSA (2017)¹².

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).

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.

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.

¹² EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9):4980

Table 8.6-3: 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	Evaluate d on EU level y/n/ Referenc e°
River, 20°C	8.39/ 7.4	6.4	21.1	5.921	FOCUS P-II calculations not performed					SFO	y EFSA (2017)
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)*		6.4	--								

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

* For 20 °C experiments.

Table 8.6-4: Summary of observed metabolites of zoxamide – water/sediment systems

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 EFSA (2017)°
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).	

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

Table 8.6-5: 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	Evaluate d on EU level y/n/ Referenc e°
River, 20°C	8.39/ 7.4	148.4	493.1	16.271	Calculations not performed					SFO	y EFSA (2017)
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)*		237	--								

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

* For 20 °C experiments.

8.6.2 Cymoxanil and its metabolites

In water-sediment studies (4 systems studied at 20°C in the laboratory in the dark in two independent studies) partitioning of cymoxanil to the sediment was insignificant. Fast degradation from the whole system was observed resulting in the range of single first order DT₅₀ of 0.1 - 1.6 days (geometric mean 0.3 day). Due to the negligible partitioning to sediment, dissipation in the water layer (0.1 - 1.5 days, geometric mean 0.3 day) was considered as almost consistent to degradation in the entire system. The major (> 10 % of AR) metabolites formed in the water-sediment systems were the following: IN-U3204 (maximum occurrence 24.7 % AR at 0.1 days after treatment (DAT)), INW3595 (27.5 % AR at 0.3 DAT), IN-KQ960 (14.3 % AR at 10 DAT), IN-T4226 (12.0 % AR at 3 DAT), metabolite fraction M5 (22.9 % AR at 1 DAT) and IN-KP533 (26.0 % AR at 10 DAT). The maximum occurrence of all of these compounds in the water phases (at least in case of one system) were above 10 % of AR, but in the sediment phases of all test systems investigated none of them were observed above 10 % of AR.

Single first order whole system degradation DT₅₀ values of the metabolites IN-U3204, IN-W3595, IN-T4226, IN-KP533, IN-KQ960, metabolite fraction M5 and the minor metabolites IN-R3273 and IN-JX915 were calculated to be 0.4, 3.0, 4.6, 2.6, 47.4, 1.4, 6.3 and 1.7 days, respectively (geometric means of 2, 3 or 4 values). Mineralisation was significant, CO₂ at the end of the experiments accounted for 45.6 % AR (after 127 days), 39.6 % AR (after 70 days), 75.5 % and 68.5% AR (after 100 days). The maximum amount of residues not extracted from sediment represented 22.5-35.2 % of AR (after 15-30 days, n=4) and decreased by the end of the experiments.

Table 8.6-6: Summary of degradation in water/sediment of cymoxanil

Cymoxanil distribution (max. sediment 3.9% after 1 day)									
Water/sediment system	pH water phase	pH sed/matrix	t °C	DegT ₅₀ /DegT ₉₀ (d) whole sys.	r ²	DegT ₅₀ /DegT ₉₀ (d) water	r ²	Method of calculation	Evaluated on EU level y/Reference
Sand	7.4	7.0/uk	20	0.5/1.7	1	0.5/1.7	1	P _{SFO}	y/EFSA Scientific Report (2008)
Sand	5.3	5.1/uk	20	1.6/5.3	0.99	1.5/5.0	0.99	P _{SFO}	
Silty clay loam	8.3	7.5/uk	20	0.1/0.2	1	0.1/0.2	1	P _{SFO}	
Silt loam	8.3	7.5/uk	20	0.2/0.5	1	0.2/0.5	1	P _{SFO}	
Geometric mean (n=4)				0.3/1.0		0.3/1.0			

Table 8.6-7: Summary of observed metabolites

IN-U3204 Water/sediment system	Max in water 24.7% AR after 0.13 d, max in sediment 0.5% AR after 3 d	Evaluated on EU level y/EFSA Scientific Report (2008)
IN-W3595 Water/sediment system	Max in water 26.1% AR after 0.25 d, max in sediment 2.3% AR after 1 d	
IN-KQ960 Water/sediment system	Max in water 13.0% AR after 1 d, max in sediment 5.5% AR after 30 d	
IN-T4226 Water/sediment system	Max in water 11.1% AR after 3 d, max in sediment 1.0% AR after 8 d	
IN-JX915 Water/sediment system	Max in water 7.2% AR after 1 d, max in sediment 1.2% AR after 1 d	
IN-R3273 Water/sediment system	Max in water 5.0% AR after 3 d, max in sediment 0.5% AR after 3 d	
IN-KP533 Water/sediment system	Max in water 20.5% AR after 10 d, max in sediment 6.5% AR after 1 d	
M5 Water/sediment system	Max in water 22.9% AR after 1d, max in sediment 0.0% AR	

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

Evaluator's Comments:	<p>Calculations of PEC_s for active substances, their metabolites and formulation used for potatoes and wine and table grapes were submitted.</p> <p>The used endpoints for both active substances DT₅₀s were agreed at the EU level. The recalculated DT₅₀ value for zoxamide (46.9 d) was accepted as a worse case.</p> <p>In PECs assessment the multiple application was taken into consideration.</p> <p>Formulation. The PECs assessment is based on single application and interception of 60%.</p> <p>The maximum PEC_s values for active substances and their metabolites are presented in following table:</p>
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Crop	Potatoes		Grape	
Use No. in GAP table	1 – 12		13 – 16	
Compound	PECs ini	PECs accum	PECs ini	PECs accum
	mg/kg			
Zoxamide	0.215	0.215	0.215	0.216
RH-127450	0.024	nr	0.024	nr
RH-24549	0.036	nr	0.036	nr
RH-163353	0.032	0.032	0.032	0.032
RH-141455	0.013	0.013	0.013	0.013
Cymoxanil	0.247	nr	0.197	nr
IN-U3204	0.147	nr	0.147	nr
IN-W3595	0.039	nr	0.039	nr
IN-JX915	0.065	nr	0.065	nr
Formulation	0.240	nr	0.241	nr

nr – not relevant

These values will be used in further risk assessment.

8.7.1 Justification for new endpoints

Zoxamide

For the DegT₅₀ 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)¹³. Thus, for PEC_{soil} calculations the slow-phase DT₅₀ of 46.9 days from the DFOP kinetics (k = 0.01477) was considered.

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 especially the formation fraction (ff) values of its transformation product RH-141455 in three different soils under aerobic conditions in the dark. In this study additional DT₅₀ values for RH-24549 and RH-141455 have been derived and taken into account to calculate updated geometric mean DegT₅₀ values of 6.84 days (n=7) for RH-24549 and 7.48 days (n=7) for RH-141455. Taking into account the three additional formation fraction (ff) values for RH-141455 developing from RH-24549, an overall arithmetic mean formation fraction (ff) of 0.504 (n=4) was calculated and used for PEC calculations.

Cymoxanil

The DT₅₀ values considered for the calculation of PECs of cymoxanil and its metabolites were taken from the EU endpoints (DAR (2007) and the EFSA Peer Review Conclusion (2008)).

¹³ EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9):4980

8.7.2 Active substance(s) and relevant metabolite(s)

Predicted environmental concentrations of the active substances zoxamide and cymoxanil and their metabolites in soil (PEC_{soil}) were calculated according to current guidelines, taking into account the EFSA (2017) concluded endpoints, the above-mentioned revised data (chapter 8.7.1), the intended worst-case GAP uses and – for metabolites – a correction for molecular weights.

For the calculation of an initial PEC_s value after multiple applications, degradation between the applications was considered according to Equation 8.7-1. A single amount of active substance that theoretically reaches the soil was calculated according to Equation 8.7-2. A standard soil bulk density of 1.5 g/cm³, as well as a standard soil layer of 5 cm, were taken into account.

Equation 8.7-1

$$PEC_{s,ini,n} = \frac{PEC_{s,ini,1} \cdot (1 - e^{-nki})}{(1 - e^{-ki})}$$

where

$PEC_{s,ini,1}$	initial PEC in soil after single application	[mg/kg]
$PEC_{s,ini,n}$	initial PEC in soil after multiple application	[mg/kg]
n	number of applications	[-]
k	degradation rate in soil	[1/d]
i	application interval	[d]

Equation 8.7-2

$$dose = Apprate * \frac{(1 - f \text{ int})}{d * bd}$$

where

PEC_{ini}	amount of active substance reaching the soil	[mg/kg]
Apprate:	dose	kg/ha]
f int	interception factor	[-]
d	soil layer	[dm]
bd	soil bulk density (1.5 g/cm ³)	[g/cm ³]

The short-term and long-term actual concentrations ($PEC_{s,act}$) and the time weighted average concentrations ($PEC_{s,twa}$) for the active substances were calculated using Equation 8.7-3 and Equation 8.7-4.

The $PEC_{s,twa}$ reflects the average concentration a species would be exposed to within a certain time period t_i starting from the day of the maximum concentration (here: directly after the last application) up to any given point of time.

Equation 8.7-3:

$$PEC_{s,act}(t) = PEC_{s,ini} * e^{(-t*k)}$$

Equation 8.7-4:

$$PEC_{s,twa}(\Delta t) = \left(\frac{\sum_{t=t_{max_i}}^{t_{max_i} + \Delta t} PEC_{s,act}(t)}{\Delta t} \right)$$

$$k = \frac{\ln 2}{DT_{50soil}}$$

where:

$PEC_{s,act}(t)$	actual concentration in soil at time t	[mg/kg]
$PEC_{s,twa}(t_i)$	time weighted average concentration in soil	[mg/kg]

$PEC_{s,ini}$	initial concentration in soil	[mg/kg]
t	time	[d]
t_{max}	time point of the beginning of integration	[d]
Δt	time interval	[d]
k	degradation rate constant in soil	[1/d]
DT_{50soil}	half-life of the substance in soil	[d]

For the degradation products the maximum amount in soil is calculated as presented in Equation 8.7-5.

Equation 8.7-5 $PEC_{ini, met.} = PEC_{ini, parent} \times \%AR \times MW_{met} / MW_{parent}$

where:

$PEC_{ini, met}$	maximum metabolite concentration in soil	[mg/kg]
$PEC_{ini, parent}$	maximum parent concentration in soil	[mg/kg]
$\%AR$	maximum occurrence of metabolite	[%]
MW_{met}	molecular mass of metabolite	[g/mol]
MW_{parent}	molecular mass of parent	[g/mol]

The predicted environmental concentration in soil that gradually attains a plateau and the subsequent decline prior to the next application was calculated following recommendations of the “FOCUS soil group”¹⁴. A standard soil bulk density of 1.5 g/cm³, as well as a soil layer of 5 cm, was considered. The following equations were used:

Equation 8.7-6 $PEC_{PLAT} = PEC_{ini} \frac{\exp(365 * \ln(2) / DT50)}{1 - \exp(365 * \ln(2) / DT50 * 365)} \frac{t}{td}$

Equation 8.7-7 $PEC_{ACCU} = PEC_{ini} + PEC_{PLAT}$

where:

PEC_{PLAT} :	Plateau concentration in soil	[mg/kg]
PEC_{ACCU} :	PEC in soil including accumulation	[mg/kg]
td	tillage depth	[cm]
d	soil depth	[cm]

The crop interception values are in line with current EFSA guidance¹⁵.

Table 8.7-1: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n / Reference ^o
Zoxamide	336.65	-	46.9 (slow phase DFOP in lab, $k=0.01477$)	EFSA (2017) considers DFOP kinetics in contrast to FOCUS (1997). Here, calculations are based on SFO kinetics using

¹⁴ 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.

¹⁵ EFSA (2014): EFSA 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 soil1. EFSA Journal 2014;12(5):3662

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT ₅₀ (days)	Value in accordance to EU endpoint y/n / Reference ^o
				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).
RH-127450	302.15	15.1	14.9 (SFO) worst-case lab	y, EFSA (2017)
RH-24549	205.0	33.8	13.8 (SFO) worst-case lab	
RH-163353	332.15	15	49.7 (SFO) worst-case lab	
RH-141455	235.02	8.4	88.5 (SFO), worst-case lab	
Cymoxanil	198.2	-	7.3*	y, (EFSA 2008)
IN-U3204	198.2	24.7	0.97*	y, (EFSA 2008)
IN-W3595	128.1	10.1	2.71*	y, (EFSA 2008)
IN-JX915	198.2	10.9	1.08*	y, (EFSA 2008)

^o EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017; 5 (9): 4980.

EFSA (2008): Conclusion regarding the peer review of the pesticide risk assessment of the active substance cymoxanil. Scientific Report 167, 17 September 2008.

*CRD considers the above table of endpoints appropriate for PEC_{soil} calculation. The DT50 values for the cymoxanil metabolites differ slightly from those in the EFSA conclusion but are more worst-case due to re-calculation of the EU-agreed values to a Q10 of 2.58.

This is not a necessary procedure, but CRD has accepted these figures for PEC_{soil} calculation, as they will not influence the assessment of PEC_{soil,max} figures, and the more conservative DT50 values in Table IIIA 9.4-2 will lead to conservative PEC_{soil} values after time 0 (time weight averages, etc).

8.7.2.1 Zoxamide and its metabolites

The following input values were used for the PEC_{soil} calculations:

Table 8.7-2: Input parameters related to application for PEC_{soil} calculations

Use No.	1-12	13-16
Crop	Potato	Grape
Application rate (g as/ha)	148.5 (zoxamide)	148.5 (zoxamide)
Number of applications/interval (d)	3/7	3/7
Crop interception (%)	1 st : 60 (BBCH 21) Following: 60/60	1 st : 60 (BBCH 14) Following: 60/60
Depth of soil layer (relevant for plateau concentration) (cm)	20 (tillage)	5 (no tillage)

In the following tables the maximum and time dependent concentrations for zoxamide and its metabolites are presented for single and multiple applications.

Table 8.7-3: PEC_{soil} for zoxamide on potatoes

PEC _{soil}	Potato
---------------------	--------

(µg/kg)		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		79.20	--	215.01	--
Short term	24h	--	--	211.86	213.43
	2d	--	--	208.75	211.87
	4d	--	--	202.67	208.78
Long term	7d	--	--	193.88	204.26
	14d	--	--	174.83	194.23
	21d	--	--	157.64	184.85
	28d	--	--	142.15	176.08
	50d	--	--	102.69	152.00
	100d	--	--	49.05	112.30
Plateau concentration (20 cm) after infintive years		--	--	0.25	--
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})		--	--	215.26	--

Table 8.7-4: PEC_{soil} for zoxamide on vine

PEC _{soil} (µg/kg)		Vine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		79.20	--	215.01	--
Short term	24h	--	--	211.86	213.43
	2d	--	--	208.75	211.87
	4d	--	--	202.67	208.78
Long term	7d	--	--	193.88	204.26
	14d	--	--	174.83	194.23
	21d	--	--	157.64	184.85
	28d	--	--	142.15	176.08
	50d	--	--	102.69	152.00
	100d	--	--	49.05	112.30
Plateau concentration (5 cm) after infintive years		--	--	0.98	--
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})		--	--	215.99	--

As can be seen from the values above (PEC_{ini} compared to PEC_{accu} values), soil accumulation of zoxamide - even after multiple year's application on the same field – does not play a role.

PEC_{soil} of metabolites

PEC calculations were performed for single and multiple applications for both GAP uses, “potatoes” and “vines”.

Table 8.7-5: PEC_{soil} for RH-127450 on potatoes

PEC _{soil} (µg/kg)		potatoes			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		10.73	--	24.08	--
Short term	24h	--	--	22.99	23.53
	2d	--	--	21.94	22.99
	4d	--	--	19.99	21.97
Long term	7d	--	--	17.39	20.55
	14d	--	--	12.55	17.70
	21d	--	--	9.07	15.37
	28d	--	--	6.55	13.46
	50d	--	--	2.35	9.34
	100d	--	--	0.23	5.13
Plateau concentration (20 cm) after infintive years		--	--	0.00	--
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		--	--	24.08	--

Table 8.7-6: PEC_{soil} for RH-127450 on vine

PEC _{soil} (µg/kg)		vine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		10.73	--	24.08	--
Short term	24h	--	--	22.99	23.53
	2d	--	--	21.94	22.99
	4d	--	--	19.99	21.97
Long term	7d	--	--	17.39	20.55
	14d	--	--	12.55	17.70
	21d	--	--	9.07	15.37
	28d	--	--	6.55	13.46
	50d	--	--	2.35	9.34
	100d	--	--	0.23	5.13
Plateau concentration (5 cm)		--	--	0.00	--

after infintive years				
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	--	--	24.08	--

Table 8.7-7: PEC_{soil} for RH-24549 on potatoes

PEC _{soil} (µg/kg)		potatoes			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		16.30	--	35.84	--
Short term	24h	--	--	34.08	34.95
	2d	--	--	32.41	34.10
	4d	--	--	29.32	32.47
Long term	7d	--	--	25.22	30.22
	14d	--	--	17.74	25.74
	21d	--	--	12.48	22.14
	28d	--	--	8.78	19.24
	50d	--	--	2.91	13.11
	100d	--	--	0.24	7.09
Plateau concentration (20 cm) after infintive years		--	--	0.00	--
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		--	--	35.84	--

Table 8.7-8: PEC_{soil} for RH-24549 on vine

PEC _{soil} (µg/kg)		vine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		16.30	--	35.84	--
Short term	24h	--	--	34.08	34.95
	2d	--	--	32.41	34.10
	4d	--	--	29.32	32.47
Long term	7d	--	--	25.22	30.22
	14d	--	--	17.74	25.74
	21d	--	--	12.48	22.14
	28d	--	--	8.78	19.24
	50d	--	--	2.91	13.11
	100d	--	--	0.24	7.09

Plateau concentration (5 cm) after infintive years	--	--	0.00	--
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})	--	--	35.84	--

Table 8.7-9: PEC_{soil} for RH-163353 on potatoes

PEC _{soil} (mg/kg)		potatoes			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		11.72	--	31.99	--
Short term	24h	--	--	31.55	31.77
	2d	--	--	31.11	31.55
	4d	--	--	30.26	31.12
Long term	7d	--	--	29.02	30.48
	14d	--	--	26.32	29.06
	21d	--	--	23.87	27.73
	28d	--	--	21.65	26.49
	50d	--	--	15.93	23.04
	100d	--	--	7.93	17.25
Plateau concentration (20 cm) after infintive years		--	--	0.05	--
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})		--	--	32.04	--

Table 8.7-10: PEC_{soil} for RH-163353 on vine

PEC _{soil} (µg/kg)		vine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		11.72	--	31.99	--
Short term	24h	--	--	31.55	31.77
	2d	--	--	31.11	31.55
	4d	--	--	30.26	31.12
Long term	7d	--	--	29.02	30.48
	14d	--	--	26.32	29.06
	21d	--	--	23.87	27.73
	28d	--	--	21.65	26.49
	50d	--	--	15.93	23.04

	100d	--	--	7.93	17.25
Plateau concentration (5 cm) after infintive years		--	--	0.20	--
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		--	--	32.19	--

Table 8.7-11: PEC_{soil} for RH-141455 on potatoes

PEC _{soil} (µg/kg)		potatoes			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		4.64	--	12.68	--
Short term	24h	--	--	12.58	12.63
	2d	--	--	12.48	12.58
	4d	--	--	12.29	12.48
Long term	7d	--	--	12.00	12.34
	14d	--	--	11.36	12.01
	21d	--	--	10.75	11.69
	28d	--	--	10.18	11.38
	50d	--	--	8.57	10.49
	100d	--	--	5.79	8.79
Plateau concentration (20 cm) after infintive years		--	--	0.19	--
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		--	--	12.87	--

Table 8.7-12: PEC_{soil} for RH-141455 on vine

PEC _{soil} (µg/kg)		vine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		4.64	--	12.68	--
Short term	24h	--	--	12.58	12.63
	2d	--	--	12.48	12.58
	4d	--	--	12.29	12.48
Long term	7d	--	--	12.00	12.34
	14d	--	--	11.36	12.01
	21d	--	--	10.75	11.69
	28d	--	--	10.18	11.38
	50d	--	--	8.57	10.49

	100d	--	--	5.79	8.79
Plateau concentration (5 cm) after infintive years		--	--	0.77	--
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})		--	--	13.45	--

As can be seen from the values above (PEC_{ini} compared to PEC_{accu} values), soil accumulation of zoxamide metabolites - even after multiple year's application on the same field – does not play a role.

8.7.2.2 Cymoxanil and its metabolites

The risk assessment provided for cymoxanil contains mainly the consolidated version of the previous product evaluation.

Six applications of Cymoxanil 33% + Zoxamide 33% WG with an application rate of 0.45 kg/ha corresponding to 148.5 g/ha Cymoxanil were assumed to be performed with an interval of 5 days (worst-case assumption) on potato. A crop interception value of 50% was considering in according to FOCUS guidelines BBCH¹⁶.

Five applications of Cymoxanil 33% + Zoxamide 33% SC with an application rate of 0.45 kg/ha corresponding to 148.5 g/ha Cymoxanil were assumed to be performed with an interval of 7 days (worst case assumption) both on grape and tomato. The applications were assumed subjected to 50% crop interception for both crops, according to FOCUS guidelines¹⁷.

For the determination of residues over time, a DT₅₀ in soil of 7.3 days (longest DT₅₀ in soil [SFO-DT₅₀ re-calculated from lab FOMC-DT₉₀ by division with 3.32, after normalisation to pF2 and 20 °C]) was assumed for Cymoxanil.

In the following tables the maximum and time dependent concentrations for cymoxanil and its metabolites are presented for single and multiple applications.

Table 8.7-13: Summary of the PEC_{soil} calculations for Cymoxanil – Potato

Method of calculation		FOCUS			
Application rate		0.45 kg product/ha (corresp. to 148.5 g/ha Cymoxanil) x 6 applications			
PEC_(s) Cymoxanil		Single application Actual [mg/kg]	Single application Time weighted average [mg/kg]	Multiple application Actual [mg/kg]	Multiple application Time weighted average [mg/kg]
Initial		0.099	-	0.247	-
Short term	24h	0.090	0.094	0.224	0.235
	2d	0.082	0.090	0.204	0.225
	4d	0.068	0.082	0.169	0.205

¹⁶ FOCUS (2002). Generic guidance for FOCUS groundwater scenarios. Version 1.1, April 2002

¹⁷ FOCUS (2002). Generic guidance for FOCUS groundwater scenarios. Version 1.1, April 2002

PEC_(s) Cymoxanil		Single application Actual [mg/kg]	Single application Time weighted average [mg/kg]	Multiple application Actual [mg/kg]	Multiple application Time weighted average [mg/kg]
Long term	7d	0.051	0.072	0.127	0.180
	14d	0.026	0.055	0.065	0.136
	21d	0.013	0.043	0.034	0.107
	28d	0.007	0.034	0.017	0.086
	42d	0.002	0.024	0.005	0.061
	100d	< 0.001	0.010	< 0.001	0.026

Table 8.7-14: Summary of the PEC_{soil} calculations for Cymoxanil – Grape and tomato

Method of calculation	FOCUS
Application rate	0.45 kg product/ha (corresp. to 148.5 g/ha Cymoxanil) x 5 applications (grape and tomato)

PEC_(s) Cymoxanil		Single application Actual [mg/kg]	Single application Time weighted average [mg/kg]	Multiple application Actual [mg/kg]	Multiple application Time weighted average [mg/kg]
Initial		0.099	-	0.197	-
Short term	24h	0.090	0.094	0.179	0.188
	2d	0.082	0.090	0.163	0.179
	4d	0.068	0.082	0.134	0.164
Long term	7d	0.051	0.072	0.101	0.144
	14d	0.026	0.055	0.052	0.109
	21d	0.013	0.043	0.027	0.085
	28d	0.007	0.035	0.014	0.069
	42d	0.002	0.024	0.004	0.048
	100d	< 0.001	0.010	< 0.001	0.021

PEC_{soil} of metabolites

In the EFSA conclusion report for Cymoxanil¹⁸ IN-U3204 occurring at a maximum of 24.7%, IN-W3595 occurring at a maximum of 10.1% and IN-JX915 occurring at a maximum of 10.9% (soil photolysis) were identified as the only potentially relevant metabolites in soil. PECs have therefore also been calculated for these metabolites.

In agreement with “risk envelope approach” (SANCO 11244/2011¹⁹), the risk assessment of Cymoxanil following the critical use of ‘Cymoxanil 33% + Zoxamide 33% WG’ on potato in Central Europe is used in order to cover all the Cymoxanil assessments on potato. 6 applications at 148.5 g a.i./ha with an interval between the applications of 5 days represent a worst case compared to 5 applications with 7 days of interval between applications.

A summary of initial PECs of Cymoxanil metabolites after application of the plant protection product Cymoxanil 33% + Zoxamide 33% WG on potato, grape and tomato is given in the Tables below.

¹⁸ Conclusion regarding the peer review of the pesticide risk assessment of the active substance Cymoxanil, EFSA Scientific Report (2008) 167, 17 September 2008

¹⁹ Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”. SANCO/11244/2011 rev.5, 14 March 2011

PEC_{soil} values were recalculated using the approach of total applied dose of the parent substance, whilst taking into account the molecular weight of the metabolite relative to the parent and the maximum occurrence of the metabolite observed in soil.

Metabolite rate = Parent total dose*molecular weight relative to parent*fraction in soil

Table 8.7-15: Summary of the PEC_{soil} calculations for IN-U3204 - Potato

Method of calculation		FOCUS	
Application rate		891*1.0*0.247 = 220.08 g/ha	
PEC_(s) IN-U3204			
		Multiple application Actual [mg/kg]	Multiple application Time weighted average [mg/kg]
Initial		0.147	-
Short term	24h	0.072	0.105
	2d	0.035	0.078
	4d	0.008	0.048
Long term	7d	0.001	0.029
	14d	< 0.001	0.015
	28d	< 0.001	0.007
	50d	< 0.001	0.004
	100d	< 0.001	0.002

Table 8.7-16: Summary of the PEC_{soil} calculations for IN-W3595 – Potato

Method of calculation		FOCUS	
Application rate		891*0.65*0.101 = 58.49 g/ha	
PEC_(s) IN-W3595			
		Multiple application Actual [mg/kg]	Multiple application Time weighted average [mg/kg]
Initial		0.039	-
Short term	24h	0.030	0.034
	2d	0.023	0.031
	4d	0.014	0.024
Long term	7d	0.007	0.018
	14d	0.001	0.011
	28d	< 0.001	0.005
	42d	< 0.001	0.003
	100d	< 0.001	0.002

Table 8.7-17: Summary of the PEC_{soil} calculations for IN-JX915 – Potato

Method of calculation		FOCUS	
Application rate		891*1.0*0.109 = 97.12 g/ha	

PEC_(s) IN-JX915		Multiple application Actual [mg/kg]	Multiple application Time weighted average [mg/kg]
Initial		0.065	-
Short term	24h	0.034	0.048
	2d	0.018	0.036
	4d	0.005	0.023
Long term	7d	0.001	0.014
	14d	< 0.001	0.007
	28d	< 0.001	0.004
	42d	< 0.001	0.002
	100d	< 0.001	0.001

Applications to grapes and tomatoes are covered by the higher use rate to potatoes, and applicant PECs have not been validated as a result.

8.7.2.3 PEC_{soil} of formulation

The formulated product ‘Cymoxanil 33% + Zoxamide 33% WG’ is a water dispersible granule (WG) formulation containing 33% (w/w) of cymoxanil and 33% (w/w) of zoxamide as nominal active substance concentrations. PEC_{soil} of the formulated product was calculated for single and multiple applications considering the same scenarios, crop interception values, soil depths, soil density and GAPs as for the active substance and its metabolites (see Table 8.7-2 provided above).

Single application values are considered relevant for the risk assessment; multiple applications and longer-term PECs are better described by active substance data. However, as an (unrealistic) worst-case assumption also PECs for multiple applications considering a half-life of 46.9 days for degradation between applications. This value was taken from the slower degrading compound zoxamide.

Table 8.7-18: PEC_{soil} for ‘Cymoxanil 33% + Zoxamide 33% WG’ on potatoes and vines

Preparation	Crop	Application pattern (g/ha)	PEC _{act} (µg/kg)	PEC _{twa21 d} (µg/kg)	Soil depth (cm)	PEC _{soil,plateau} (µg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (µg/kg)
‘Cymoxanil 33% + Zoxamide 33% WG’	Potato	1*450 g/ha*	240	206.33	20	0.27	240.27
‘Cymoxanil 33% + Zoxamide 33% WG’	Vine	1*450 g/ha*	240	206.33	5	1.10	241.10
‘Cymoxanil 33% + Zoxamide 33% WG’	Potato	3*450 g/ha* (7 days interval)	651.55	560.14	20	2.97	654.53
‘Cymoxanil 33% + Zoxamide 33% WG’	vine	3*450 g/ha* (7 days interval)	651.55	560.14	5	0.74	652.30

** DegT₅₀ of 46.9 d for zoxamide

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

<p>Evaluator's Comments:</p>	<p>The submitted PEC_{gw} assessment was accepted.</p> <p>The application dates were accepted; an early and late applications in potatoes and grapes were taken into consideration. The recommended FOCUS models were used: FOCUS PELMO, FOCUS PEARL and FOCUS MACRO.</p> <p>Zoxamide. All used endpoints were agreed at the EU level or recalculated with new values. Calculations of PEC_{gw} for active substance and its relevant metabolite were provided in Tier 1 with PUF = 0. The maximum PEC_{gw} values for active substance and their metabolites, except RH-141455, were below the trigger value of 0.1 µg/L. For RH-141455, the max PEC_{gw} value of 0.622 µg/L was assessed and its relevance will be discussed in Section 10. Additionally, the refinement for PEC_{gw} assessment for metabolite RH-141455 was provided.</p> <p>Cymoxanil. Most of used endpoints were agreed at the EU level; the only new endpoints for metabolite IN KQ960 were used. Calculations of PEC_{gw} for active substance were provided in Tier 1 with PUF = 0.5 (agreed at the EU level) and PEC_{gw} for relevant metabolite were provided in Tier 1 with PUF = 0. In PEC_{gw} assessment the previous models version was used. As the final results of PEC_{gw} assessment do not exceed the trigger value of 0.1 µg/L, the submitted calculations were accepted. The maximum PEC_{gw} values for active substance and its metabolites were below the trigger value of 0.1 µg/L.</p>
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8.8.1 Justification for new endpoints

Zoxamide

EFSA (2017) set a geometric mean value of 5.4 days (n=4) for the metabolite RH-24549. However, this value did not include the results of Derz (2020). Therefore, an overall geometric mean value of 6.84 days (n=7) including the results of Derz (2020) is considered **in addition** for the simulations.

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 [¹⁴C]-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 overall geometric mean DegT₅₀ value of 7.48 days (n=7). These values were used **in addition** for groundwater simulations.

Finally, in EFSA (2017) the arithmetic mean K_{foc} is suggested for all substances. However, here the respective geometric mean values are used according to current EFSA guidelines (EFSA 2014)²⁰.

²⁰ EFSA (2014): EFSA 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 soil1. EFSA Journal 2014;12(5):3662

Cymoxanil

The DT₅₀ values considered for the calculation of PECs were taken from the EU endpoints for cymoxanil and its metabolites, apart from new Koc and DT₅₀ values that were used for higher tier assessment for metabolite IN KQ960 PEC_{gw} calculation.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

For justification, please refer to chapter 8.8.1.

Table 8.8-1: Input parameters related to active substance zoxamide and its metabolite(s) for PEC_{gw} calculations

Compound	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	Value in accordance with EU endpoint y/n/ Reference°
Molecular weight (g/mol)	336.65	302.15	205.0	332.15	235.02	y (EFSA, 2017)
Water solubility (mg/L):	0.681	1000 ⁺	1000 ⁺	1000 ⁺	1000 ⁺	
Saturated vapour pressure (Pa):	1.3 x 10 ⁻⁵ (25°C)	-*	-*	-*	-*	
DT ₅₀ in soil (d)	5.5 (geometric mean, n=6)	5.2 (geometric mean, n=5)	5.4 (geometric mean, n=4)	10.8 (geometric mean, n=4)	19.6 (geometric mean, n=4)	y EFSA (2017)
DT ₅₀ in soil (d) - Refined	5.5 (geometric mean, n=6)	5.2 (geometric mean, n=5)	6.84 (geometric mean, n=7; including Derz 2020)	10.8 (geometric mean, n=4)	7.48 (geometric mean, n=7; including Derz 2020)	partly y EFSA (2017)
K _{foc} (mL/g)	1179 (geometric mean, n=4)	593 (geometric mean, n=3)	90.55 (worst-case, n=3)	67 (geometric mean, n=3)	2.8 (geometric mean, n=3)	n, geometric mean values considered
K _{om} (mL/g)	684 (geometric mean, n=4)	344 (geometric mean, n=3)	52.5 (worst-case, n=3)	39 (geometric mean, n=3)	1.6 (geometric mean, n=3)	n, geometric mean values calculated from K _{foc}
1/n	0.970 (arithmetic mean, n=4)	0.9** (default)	0.811 (arithmetic mean, n=3)	0.892 (arithmetic mean, n=3)	1.0 [#]	y (EFSA, 2017)
Plant uptake factor	0*	0*	0*	0*	0*	
Formation fraction	--	0.24 (from zoxamide)	0.38 (from zoxamide)	0.18 (from zoxamide)	1 (default)	y EFSA (2017)
Formation fraction - Refined	--	0.24 (from zoxamide)	0.38 (from zoxamide)	0.18 (from zoxamide)	0.504 (from RH-24549; arithm. mean, n= 4; including Derz 2020) [%]	partly y EFSA (2017)
Conversion factor (MACRO) all from zoxamide	--	0.215	0.231	0.178	0.265 [%]	y EFSA (2017)
Conversion factor (MACRO) all from zoxamide - Refined	--	0.215	0.231	0.178	0.134 [%]	partly y EFSA (2017)

- ° EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9): 4980
- * worst-case
- + worst-case default (in the absence of measured values)
- ** since the 1/n of 0.523 was considered unreliable, a default value was used
- # adsorption of RH-141455 on soil was very low and therefore no desorption kinetics and adsorption/ desorption isotherms were determined; hence a Freundlich exponent of 1 was set by EFSA (2017)
- % Macro cannot handle secondary metabolites. Therefore the formation fraction for Macro was calculated as follows:

$$FF(\text{zoxamide} \rightarrow \text{RH-141455}) = FF(\text{zoxamide} \rightarrow \text{RH24549}) * FF(\text{RH24549}) * \text{Molar ratio}(\text{zoxamide} \rightarrow \text{RH24549}) = 0.38 * 0.504 * (235.02/336.65) = 0.134$$
- %% Macro cannot handle secondary metabolites. Therefore the formation fraction for Macro was calculated as follows:

$$FF(\text{zoxamide} \rightarrow \text{RH-141455}) = FF(\text{zoxamide} \rightarrow \text{RH24549}) * FF(\text{RH24549}) * \text{Molar ratio}(\text{zoxamide} \rightarrow \text{RH24549}) = 0.38 * 1 * (235.02/336.65) = 0.265$$

Table 8.8-2: Input parameters related to active substance cymoxanil and its metabolite(s) for PEC_{gw} calculations

Compound	Cymoxanil	IN-U3204	IN-W3595	IN-KX915	IN-KQ960	Value in accordance with EU endpoint y/n/ Reference°
Molecular weight (g/mol)	198.2	198.2	128.1	198.2	216.2	y (EFSA, 2008)
Water solubility (mg/L):	783 (20°C, pH 7)	783 (20°C, pH 7)	783 (20°C, pH 7)	783 (20°C, pH 7)	783 (20°C, pH 7)	y (EFSA, 2008)
Saturated vapour pressure (Pa):	1.5 x 10 ⁻⁴ (20°C)	-	-	-	-	(EFSA, 2008)
DT ₅₀ in soil (d)	1.7 ^A +/7.3 ^B	0.38 ^A	2.71 ^B	1.08 ^B	3.49*	y
K _{foc} (mL/g)	43.6 ^C	27.9 ^D	pH dependent Koc acid=33.3 Koc basic=2.3 pKa = 5.2	16.1 ^C	5.13*	(EFSA, 2008)
1/n	1 ^E	1 ^E	1 ^E	1 ^E	0.97*	y
Plant uptake factor	0.5	0	0	0	0	(EFSA, 2008)
Formation fraction	-	0.36	0.15	0.1	0.16 from IN-U3204)	y

^A) geometric mean, value recalculated with normalisation topF2, 20°C with Q10 of 2.58

⁺⁺ The geomean DT50 value for cymoxanil in table differs slightly from that reported in the EFSA conclusion. For the purposes of providing a conservative groundwater assessment for metabolites, the correct geomean value of 1.2 days from the EFSA Scientific Report (2008) 167, pg 84 has been used. Typically, the use of a worst-case DT50 for the parent compound (cymoxanil) is inappropriate for groundwater modelling. Whilst a longer parent DT50 will be conservative for parent PECs, conservatism is already built into the PEARL model. In addition, a long DT50 will decrease the rate at which metabolites are created, and along with simultaneous metabolite degradation will possibly lead to unrealistically low metabolite PECs.

CRD also modelled the parent and metabolite PEC_{gw} using the EFSA agreed parent DT50 of 1.2 days to ensure this was not the case. In this case, the parent DT50 made a negligible difference to metabolite PECs

Anyway, the applicant PECs can be regarded as accurate.

^B) worst case value, value recalculated with normalisation topF2, 20°C with Q10 of 2.58

^C) arithmetic mean

^D) values calculated by HPLC method

^E) PRAPeR 32 agreed default value

* Not consolidated endpoint. Since Annex I inclusion new studies and/or information on the active substance have been generated and as a result there are new end-points which are used in the risk assessment.

Transformation rates from the parents were considered for metabolites simulations. While metabolites IN-U3204, IN-W3595 and IN-JX915 were considered to be formed from parent Cymoxanil, the parent of metabolite IN-KQ960 was considered to be metabolite IN-U3204, according to EFSA conclusions¹³.

Since 3 studies were available for IN-U3204, the geometric mean DT₅₀ value was used for the simulations. The geometric mean value for IN-KQ960 DT₅₀ of 2.76 days coming from the new studies performed and presented into this document (please refer to Point 9.7.1, Clark 2010a) was used.

For the other metabolites the worst-case value was instead taken into account. All these values were calculated considering a Q_{10} factor of 2.58 according to EFSA Opinion (2007²¹). 1/n values of 1 and plant uptake coefficient of 0 were used into the modelling for IN-U3204, IN-W3595 and IN-JX915 following EFSA indications⁹. For IN-KQ960 1/n value of 0.97, corresponding to the geometric mean coming from Clark 2010b was used.

Adsorption of metabolite IN-W3595 resulted to be dependent on the soil pH following a sigmoid curve; a pKa value of 5.2 was derived from this curve and Koc values for each FOCUS groundwater scenario were calculate according to the top soil pH (please refer to Cymoxanil Draft Assessment Report, Volume 3, Annex B.8, page 81, October 2007). Koc values used are shown in Table 8.8-3.

Table 8.8-3: Obtained K_{oc} values for IN-W3595 depending on the pH of the topsoil of each FOCUS groundwater scenario

FOCUS scenario	Topsoil pH (KCl)	IN-W3595 - K_{oc} [L kg ⁻¹]
Châteaudun	7.3	2.6
Hamburg	5.7	10.2
Jokioinen	5.5	13.2
Kremsmünster	7.0	2.9
Okehampton	5.1	20.1
Piacenza	6.3	4.8
Porto	4.2	30.6
Sevilla	6.6	3.6
Thiva	7.0	2.9
Arithmetic mean KOC from batch experiments (n = 4)	-	9.2

The 80th percentile concentrations of zoxamide, cymoxanil and their metabolites at 1 m soil depth simulated with the models FOCUS PEARL, PELMO and MACRO and are given in the following chapters.

8.8.2.1 Zoxamide and its metabolites

Table 8.8-4: Input parameters related to application for PEC_{gw} calculations

Use No.	1-12	13-16
Crop	potato	grape
Application rate (.0594g as/ha)	148.5 (zoxamide)	148.5 (zoxamide)
Number of applications/interval (d)	3/7	3/7
Relative application date	13 / 20 / 27 (early: relative to emergence) -21/-14/-7 (late: relative to harvest)	17 / 24 / 31 (early: relative to emergence) -42/-35/-28 (late: relative to harvest)

²¹ EFSA Journal (2007) 622, 1-32. Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default Q_{10} value used to describe the temperature effect on transformation rates of pesticides in soil

Crop interception (%)	Early applications: 1 st : 60 (BBCH 21) Following: 60/60 Late applications: 1 st : 85 (BBCH 81) Following: 85/85	Early applications: 1 st : 60 (BBCH 14) Following: 60/60 Late applications: 1 st : 75 (BBCH 85) Following: 75/75
actual appl. rate (g/ha)	Early: 3 * 59.4 (zoxamide + cymoxanil) Late: 3 * 22.3 (zoxamide + cymoxanil)	Early: 3 * 59.4 (zoxamide + cymoxanil) Late: 3 * 37.1 (zoxamide + cymoxanil)
Frequency of application	Annual	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v. 5.5.4	

The application window for grapes is very large (e.g., applications possible from March to November at Sevilla). Therefore, two separate simulations were performed – for early and late applications. Also, for potatoes (e.g., applications possible from form May to September at Piacenza) early and late applications were performed for the same reason.

Table 8.8-5: Application dates used for groundwater risk assessment *

Crop	Scenario	first application dates used in modelling (early)	last application dates used in modelling (late) °
Potato (BBCH 21–89)	Châteaudun	13 May	25. August
	Hamburg	23 May	8 September
	Jokioinen	18 June	18 September
	Kremsmünster	23 May	8 September
	Okehampton	13 May	25. August
	Piacenza	3 May	3 September
	Porto	28 March	8 June
	Sevilla	13 Feb	24. May
	Thiva	14 March	23. July
Grape (BBCH 14-89)	Châteaudun	18 April	04 October
	Hamburg	18 May	02 October
	Jokioinen	-	
	Kremsmünster	18 May	02 October
	Okehampton	-	
	Piacenza	18 April	04 October
	Porto	01 April	02 September
	Sevilla	17 April	02 November
	Thiva	01 April	22 September

* Dates defined using AppDateVersion 3.06 (28 June 2019) relative application dates based on Châteaudun

° considering a PHI of 7 days for potatoes and 28 days for grapes, respectively

The results are summarised in the following for PELMO, PEARL and MACRO, respectively.

Independent from the computer model, the crop and the application scenario, the groundwater concentrations for zoxamide, RH-127450, RH-24549, and RH-163353 were <0.001 µg/L.

When considering the refinement for metabolite RH-141455, concentrations were simulated below 0.75 µg/L and above the drinking water trigger of 0.1 µg/L - independently from the computer model and the crop. The maximum concentration derived was 0.622 µg/L (PELMO, vine late, Hamburg).

Thus, no unacceptable risk of groundwater contamination is expected following annual applications of zoxamide and its metabolites for the intended uses (see also dRR Part B Section 10).

Table 8.8-6: PEC_{gw} for zoxamide and its metabolite(s) (with FOCUS PELMO 5.5.3)

Crop	Scenario	Zoxamide EU- Endpoints & Refinement	RH-127450 EU- Endpoints & Refinement	RH-24549 EU- Endpoints & Refinement	RH-163353 EU- Endpoints & Refinement	RH-141455 EU- Endpoints	RH-141455 Refinement
Potato early	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.769	0.010
	Hamburg	<0.001	<0.001	<0.001	<0.001	1.813	0.071
	Jokionen	<0.001	<0.001	<0.001	<0.001	4.179	0.374
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	1.289	0.052
	Okehampton	<0.001	<0.001	<0.001	<0.001	1.288	0.054
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.417	0.008
	Porto	<0.001	<0.001	<0.001	<0.001	0.362	0.007
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.069	0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.182	<0.001
Potato late	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.446	0.019
	Hamburg	<0.001	<0.001	<0.001	<0.001	1.866	0.287
	Jokionen	<0.001	<0.001	<0.001	<0.001	2.093	0.458
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	1.080	0.137
	Okehampton	<0.001	<0.001	<0.001	<0.001	1.106	0.128
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.786	0.097
	Porto	<0.001	<0.001	<0.001	<0.001	0.159	0.003
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.020	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.065	0.001
Vine early	Châteaudun	<0.001	<0.001	<0.001	<0.001	1.281	0.025
	Hamburg	<0.001	<0.001	<0.001	<0.001	2.111	0.081
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	1.738	0.090
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.914	0.046
	Porto	<0.001	<0.001	<0.001	0.001	0.680	0.024
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.289	0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.333	0.001
Vine late	Châteaudun	<0.001	<0.001	<0.001	<0.001	1.390	0.111
	Hamburg	<0.001	<0.001	<0.001	<0.001	3.641	0.622
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	1.710	0.244

	Piacenza	<0.001	<0.001	<0.001	<0.001	2.018	0.282
	Porto	<0.001	<0.001	<0.001	<0.001	0.952	0.105
	Sevilla	<0.001	<0.001	<0.001	<0.001	1.107	0.157
	Thiva	<0.001	<0.001	<0.001	<0.001	1.060	0.083

Bold = highest value per crop

Table 8.8-7: PEC_{gw} for zoxamide and its metabolite(s) (with FOCUS PEARL 4.4.4)

Crop	Scenario	Zoxamide EU- Endpoints & Refinement	RH-127450 EU- Endpoints & Refinement	RH-24549 EU- Endpoints & Refinement	RH-163353 EU- Endpoints & Refinement	RH-141455 EU- Endpoints	RH-141455 Refinement
Potato early	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.995	0.013
	Hamburg	<0.001	<0.001	<0.001	<0.001	3.102	0.146
	Jokionen	<0.001	<0.001	<0.001	<0.001	4.647	0.387
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	1.331	0.039
	Okehampton	<0.001	<0.001	<0.001	<0.001	1.329	0.044
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.394	0.004
	Porto	<0.001	<0.001	<0.001	<0.001	0.253	0.002
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.038	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.215	<0.001
Potato late	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.633	0.029
	Hamburg	<0.001	<0.001	<0.001	<0.001	2.449	0.364
	Jokionen	<0.001	<0.001	<0.001	<0.001	2.131	0.409
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.962	0.103
	Okehampton	<0.001	<0.001	<0.001	<0.001	1.183	0.126
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.950	0.095
	Porto	<0.001	<0.001	<0.001	<0.001	0.051	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.021	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.190	0.004
Vine early	Châteaudun	<0.001	<0.001	<0.001	<0.001	1.465	0.030
	Hamburg	<0.001	<0.001	<0.001	<0.001	2.416	0.065
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	1.322	0.050
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.608	0.032
	Porto	<0.001	<0.001	<0.001	0.001	0.424	0.090
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.565	0.004
	Thiva	<0.001	<0.001	<0.001	<0.001	0.286	<0.001
Vine late	Châteaudun	<0.001	<0.001	<0.001	<0.001	1.582	0.040
	Hamburg	<0.001	<0.001	<0.001	<0.001	3.109	0.184
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	1.517	0.051

	Piacenza	<0.001	<0.001	<0.001	<0.001	1.995	0.070
	Porto	<0.001	<0.001	<0.001	<0.001	1.032	0.227
	Sevilla	<0.001	<0.001	<0.001	<0.001	1.073	0.034
	Thiva	<0.001	<0.001	<0.001	<0.001	1.033	0.011

In line with the Working Document of the Central Zone in the Authorisation of Plant Protection Products - Part B section 8 (Environmental Fate and Behaviour) rev. 1.1 (2018), MACRO simulations are not necessary for zoxamide, RH127450, RH-24549 and RH-163353 since the PEC_{GW} values for FOCUS PEARL and FOCUS PELMO are <0.001 µg/L. The values for RH-141455 (and for the parent for completeness) are presented in the following.

Table 8.8-8: PEC_{gw} for zoxamide and its metabolite(s) (with FOCUS MACRO 5.5.4)

Crop	Scenario	Zoxamide EU-Endpoints & Refinement	RH-141455 EU-Endpoints	RH-141455 Refinement
Vine early	Châteaudun	<0.001	0.271	0.00453
Vine late	Châteaudun	<0.001	0.661	0.0549
Potato early	Châteaudun	<0.001	0.231	0.00412
Potato late	Châteaudun	<0.001	0.227	0.0134

8.8.2.2 Cymoxanil and its metabolites

The risk assessment provided for cymoxanil contains the consolidated version of the previous product evaluation, since that part does not require any update. The risk assessment is therefore based on the worst-case application pattern, related to the previous product GAP.

The PEC of cymoxanil and its metabolites in ground water has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3 models and the K_{oc} values established in the EU review and based on new data provided for IN-KQ960. Only metabolites IN-U3204, IN-W3595, IN-JX915 and IN-KQ960 are considered to be of relevance for groundwater assessment.

It must be considered that metabolite IN-KQ960 falls within the definition of “major metabolite” only considering a non-European representative soil (please refer to Cymoxanil DAR Addendum of September 2008, Volume 3, Section B.8, Chapter B.8.1). This metabolite was observed only in the Japanese “Black Andosol” at level two times consecutively greater than 5% AR (namely 6.25% at day 3 and 5.3% at day 7) but it was never detected at level exceeding 0.6% in any of the eight European or US laboratory soil degradation studies. Considering that volcanic soils representativeness in EU scenario is very limited, this metabolite should not be considered as major in soil.

In spite of the previous consideration, PEC_{gw} for IN-KQ960 were calculated.

In Cymoxanil EFSA conclusions²², clarification of the potential intermediates in the transformation pathway of ethyl urea route and assess their relevance were required. According to SANCO 221/2000²³, a degradation product which may aspect to occur in groundwater as a result of a soil degradation study or a lysimeter study doesn't require any assessment if it is an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern. Ethyl urea and its possible metabolites (e.g. urea – CH₄N₂O- or amino ethane – C₂H₇N-) fall into the previous definition, and therefore they don't need any further assessment.

6 applications with 0.45 kg/ha of Cymoxanil 33% + Zoxamide 33% WG (corresponding to 148.5 g cymoxanil/ha and 148.5 g zoxamide/ha) were considered on potato and 5 both on grape and tomato.

For potato following FOCUS indications²⁴ according to BBCH values (from BBCH 21), a foliar interception value of 50% was taken into account for the first 4 applications, while for the 5th and 6th applications the 80% of foliar interception was considered. Treatments were simulated starting from 7 days after emergence. Irrigation was also taken into account for those scenarios where it is foreseen (irrigation scheme F).

For grape, following FOCUS indications²⁵ according to BBCH values, a foliar interception value of 50% was taken into account for the first 3 applications, while for the 4th and the 5th applications an interception of 60% was considered. Treatments were simulated starting from 7 days after emergence. Irrigation was also taken into account for those scenarios where it can be considered (irrigation scheme F).

According to EFSA conclusions the geometric mean DT₅₀ SFO value of 1.3d should be used for simulations. Normalising this value considering a Q10 factor of 2.58, a geometric mean value of 1.7 can be calculated. Anyway, since into cymoxanil DAR²⁶ also simulations considering the worst case DT₅₀ value of 7.3d (highly conservative risk assessment taking into account pH dependent degradation of cymoxanil) were performed, simulations with this value of DT₅₀ in soil were performed in the present document. Also simulations with a DT₅₀ value of 1.7 d were run, but representing a best case, they were not reported. They will be provided under request.

The arithmetic means of K_{oc} and 1/n were used into the model runs. A plant uptake factor of 0.5 was taken into account for the parent.

Table 8.8-9: Key application data used in the FOCUS GW calculations on potato

Input parameter	Value
Crop scenario	Potato
FOCUS scenarios	Chateaudun, Hamburg, Jokioinen, Kremsmunster, Okehampton, Piacenza, Porto, Sevilla, Thiva
Application rate	0.45 kg Cymoxanil 33% + Zoxamide 33% WG corresp. to 148.5 g cymoxanil/ha
Interception by plants*	1 st -4 th appl. (BBCH 14): 50% 5 th -6 th appl.: 80%
Application rate (considering plant interception)	1 st -4 th appl.: 0.074 kg a.s./ha 5 th -6 th appl.: 0.029 kg a.s./ha

²² Conclusion regarding the peer review of the pesticide risk assessment of the active substance Cymoxanil, EFSA Scientific Report (2008) 167, 17 September 2008

²³ SANCO/221/2000- rev.10-final (25 February 2003). Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC.

²⁴ FOCUS (2002). Generic guidance for FOCUS groundwater scenarios. Version 1.1, April 2002

²⁵ FOCUS (2002). Generic guidance for FOCUS groundwater scenarios. Version 1.1, April 2002

²⁶ Cymoxanil Draft Assessment Report. Volume 3, Annex B. October 2007. Rapporteur Member State: Austria.

Input parameter	Value
Application method	Soil application
Mode of application	Every year
Number of applications per year	6
Time between applications	5 days
Application timing	1 st application at BBCH 21 ^{A)}
Region of application	Europe

* in accordance with: Report of the FOCUS Groundwater Scenarios Workgroup “FOCUS groundwater scenarios in the EU review of active substances”, EC Document Reference SANCO/321/2000 rev.2, 202pp, 2000

^{A)} 7 days after emergence in each scenario

Table 8.8-10: Key application data used in the FOCUS GW calculations on grape

Input parameter	Value
Crop scenario	grape
FOCUS scenarios	Chateaudun, Hamburg, Kremsmunster, Piacenza, Porto, Sevilla, Thiva
Application rate	0.45 kg Cymoxanil 33% + Zoxamide 33% WG corresp. to 148.5 g cymoxanil/ha
Interception by plants*	1 st -3 rd appl. (BBCH 14): 50% 4 th -5 th appl.: 60%
Application rate (considering plant interception)	1 st – 3 rd appl.: 0.074 kg a.s./ha 4 th -5 th appl.: 0.059 kg a.s./ha
Application method	Soil application
Mode of application	Every year
Number of applications per year	5
Time between applications	7 days
Application timing	1 st application at BBCH 14 ^{A)}
Region of application	Europe

* in accordance with: Report of the FOCUS Groundwater Scenarios Workgroup “FOCUS groundwater scenarios in the EU review of active substances”, EC Document Reference SANCO/321/2000 rev.2, 202pp, 2000

^{A)} 7 days after emergence in each scenario

Table 8.8-11: Potato application dates used in modelling (1st application date: 7 days after emergence)

Crop	Scenario	Application timing					
		1 st appl.	2 nd appl.	3 rd appl.	4 th appl.	5 th appl.	6 th appl.
Potato	Châteaudun	7 May	12 May	17 May	22 May	27 May	1 June
	Hamburg	17 May	22 May	27 May	1 June	6 June	11 June
	Jokioinen	12 June	17 June	22 June	27 June	2 July	7 July
	Kremsmünster	17 May	22 May	27 May	1 June	6 June	11 June
	Okehampton	7 May	12 May	17 May	22 May	27 May	1 June
	Piacenza	27 April	2 May	7 May	12 May	17 May	22 May
	Porto	22 March	27 March	1 April	6 April	11 April	16 April
	Sevilla	7 Febr.	12 Febr.	17 Febr.	22 Febr.	27 Febr.	4 March
	Thiva	8 March	13 March	18 March	23 March	28 March	2 April

Table 8.8-12: Grape application dates used in modelling (1st application date: 7 days after emergence)

Crop	Scenario	Application timing				
		1 st appl.	2 nd appl.	3 rd appl.	4 th appl.	5 th appl.
Grape	Châteaudun	8 April	15 April	22 April	29 April	6 May
	Hamburg	8 May	15 May	22 May	29 May	5 June
	Kremsmünster	8 May	15 May	22 May	29 May	5 June
	Piacenza	8 April	15 April	22 April	29 April	6 May
	Porto	22 March	29 March	5 April	12 April	19 April
	Sevilla	7 April	14 April	21 April	28 April	5 May
	Thiva	22 March	29 March	5 April	12 April	19 April

Results obtained are reported in Tables below.

Table 8.8-13: PEC_{GW} for potato (first treatment 7 days after emergence) at 1 m soil depth for Cymoxanil and its metabolites

Model	Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth (µg L ⁻¹)				
			Cymoxanil	IN-U3204	IN-W3595	IN-JX915	IN-KQ960
PELMO 3.3.2	Potato	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Jokioinen	< 0.001	< 0.001	0.001	< 0.001	0.001
		Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Piacenza	< 0.001	< 0.001	0.001	< 0.001	< 0.001
		Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

		Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
PEARL 3.3.3	Potato	Châteaudun	< 0.001	< 0.001	0.001*	< 0.001	< 0.001
		Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	0.001
		Jokioinen	< 0.001	< 0.001	0.002	0.001	0.004
		Kremsmünster	< 0.001	< 0.001	0.001	< 0.001	< 0.001
		Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Piacenza	< 0.001	< 0.001	0.001*	< 0.001	0.001*
		Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

* results of irrigated scenarios

Table 8.8-14: PEC_{GW} for grape (first treatment 7 days after emergence) at 1 m soil depth for Cymoxanil and its metabolites

Model	Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth (µg L ⁻¹)				
			Cymoxanil	IN-U3204	IN-W3595	IN-JX915	IN-KQ960
PELMO 3.3.2	Grape	Châteaudun	< 0.001	< 0.001	0.002	< 0.001	< 0.001
		Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Kremsmünster	< 0.001	< 0.001	0.002	< 0.001	< 0.001
		Piacenza	< 0.001	< 0.001	0.004	< 0.001	0.001
		Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
PEARL 3.3.3	Grape	Châteaudun	< 0.001	< 0.001	0.006*	< 0.001	0.003*
		Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	0.001
		Kremsmünster	< 0.001	< 0.001	0.001	< 0.001	< 0.001
		Piacenza	0.003	< 0.001	0.005*	< 0.001	0.004*
		Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Sevilla	< 0.001	< 0.001	0.002*	< 0.001	0.001*
		Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

* results of irrigated scenarios

For all scenarios and crops, the 80th percentile concentrations of Cymoxanil calculated using PELMO 3.3.2 were <0.001 µg/L, also considering the worst case pseudo SFO DT₅₀ value of 7.3 days.

Using PEARL 3.3.3 the 80th percentile concentrations were < 0.001 µg/L with the exception of Piacenza scenario for tomato and grape, when irrigation (type F) is considered. Concentrations of 0.003 µg/L and 0.001 µg/L were predicted respectively on grape and tomato.

Cymoxanil is not predicted to leach into groundwater following a 26-years period after applications of Cymoxanil 33% + Zoxamide 33% WG on grape and tomato. For all scenarios considered, the 80th percentile reporting endpoints were well below the regulatory threshold value of 0.1 µg/L.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

Evaluator's Comments:	The submitted PEC _{sw} and PEC _{sed} calculations were accepted.					
	The proposed crops and relevant application rates were taken into consideration. Additionally, for vines, the early and late application time and lower application rate of zoxamide of 3x132 g/ha instead of 3x148.5 g/ha was taken into account.					
	The early and late application were provided and justification submitted by the Applicant was accepted: <i>The late application dates in October/November (valid for southern EU / Greek conditions) are not relevant for the central zone and the here intended GAP use on potatoes with an application timing April to September; they are therefore not considered further.</i>					
	The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3 and Step 4. In Step 3 and Step 4 the proposed refinement for foliar half-life was accepted (Tier 2). The residue studies were evaluated and accepted in Section 7. The DT ₅₀ value of 3.9 d was calculated in accordance with recommended guidance using the relevant tool KINGUII.					
	Additionally, PEC _{assessment} in Tier 1 with foliar half-life of 10 d were added.					
	The mitigation measures were proposed: 5m, 10m, 15m and 20 m of non-sprayed and vegetated buffer strips. The drift reduction nozzles were used, too.					
	Zoxamide. In Step 3 and Step 4 modelling application rates of 3 x 148.5 g a.s./ha and 3 x 148.5 g a.s./ha (and 3 x 132.0 g a.s./ha) for potatoes and vines, respectively were used.					
The max PEC _{sw} for Central Zone and Poland with relevant mitigation measure are presented in the table below.						
Tier 2.						
	Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Central Zone Max PEC _{sw} (µg/l)	Poland Max PEC _{sw} (µg/l)
	Potatoes	3 x 148.5	10	10	0.312 R3 stream	0.243 R1 stream
		1 x 148.5	5	5	0.320 R3 stream	0.312 R1 stream
	Vines, early	3 x 148.5	20	20	0.263 R4 stream	not considered*
		1 x 148.5	10	10	0.220 R3 stream	not considered*
	Vines, late	3 x 148.5	20	20	0.327 R4 stream	not considered*
		1 x 148.5	20	20	0.244	not

					R3 stream	considered*
Vines, early	3 x 132	15	15	0.342	R4 stream	not considered*
	1 x 132	10	10	0.195	R3 stream	not considered*
Vines, late	3 x 132	20	20	0.290	R4 stream	not considered*
	1 x 132	15	15	0.335	R4 stream	not considered*

* in accordance with Applicant's decision, grapes are not considered to be authorised in Poland.

Metabolites of zoxamide. The relevant metabolites were taken into consideration. The max PEC_{sw} values are presented in the table below.

Metabolites	Crop	Application rate ¹ g a.s./ha	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
RH-127450	Potatoes	3 x 148.5	5.004	29.00
RH-24549	Potatoes	3 x 148.5	4.095	3.703
RH-163353	Potatoes	3 x 148.5	7.188	4.874
RH-141455	Potatoes	3 x 148.5	1.498 2.319	0.042 0.029
RH-139432	Potatoes	3 x 148.5	3.915	0.391

Cymoxanil. Most of input parameters used in PEC_{sw/sed} assessment were agreed at the EU level. The used value of DT₅₀ in soil for active substance presented in Table 8.9-43 is higher than agreed one (LoEP, 2008); as represents a worse case – was accepted for modelling.

In Step 1 & 2 modelling application rates of 6 x 148.5 g a.s./ha for potatoes and 5 x 148.5 g a.s./ha vines were used. The late application in vines covers the early application. The max PEC_{sw} representative for Central Zone (Northern EU) are presented in the table below.

Crop	Application rate g a.s./ha	Max PEC _{sw} (µg/l)	Max PEC _{sed} (µg/kg)
Potatoes	6 x 148.5	1.053	0.459
Vines, early	5 x 148.5	3.597	1.153
Vines, late	5 x 148.5	3.285	1.271

Metabolites of cymoxanil. The relevant metabolites were taken into consideration. The max PEC_{sw} values are presented in the table below.

Metabolites	Crop	Application rate ¹ g a.s./ha	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
IN-U3204	Vines, late	5 x 148.5	0.811	0.026
IN-W3595			0.690	0.055
IN-KQ960			2.249	0.114
IN-T4226			1.088	0.180
IN-JX915			1.832	0.130
IN-R3273			2.576	0.959
IN-KP531			1.791	0.222
M5			0.776	0.029

Formulation. The drift exposure was assessed using the Drift Calculator in SWASH model. The PEC_{sw} results with proposed mitigation measures are presented in Table 8.9-56

Crop	Rate (g/ha)		Single application	Multiple applications			
		Drift reduction	0 %	0 %	50 %	75 %	90 %
		Buffer distance [m]	PEC _{sw} [µg formulation/L]				
Vine early	3*450	3 m (standard)	2.5776	3.9759	1.9880	0.9940	0.3976
		10 m	0.5409	0.7465	0.3732	0.1866	0.0746
		20 m	0.1842	0.2355	0.1177	0.0589	0.0235
Vine late	3*450	3 m (standard)	7.7595	11.1922	5.5961	2.7980	1.1192
		10 m	1.6994	2.4040	1.2020	0.6010	0.2404
		20 m	0.5961	0.8321	0.4160	0.2080	0.0832
Potatoes	3*450	1-2 m (standard)	2.8911	3.5584	1.7792	0.8896	0.3558
		5 m	0.8286	0.9417	0.4708	0.2354	0.0942
		10 m	0.4157	0.4938	0.2469	0.1234	0.0494

The relevant mitigation measure will be recommended in ecotoxicological section.

Predicted Environmental Concentrations of the parent compound and its relevant metabolites in surface water and sediment (PEC_{sw}, PEC_{sed}) were calculated in a stepwise approach with FOCUS SW following the Guidance of the FOCUS Surface Water Report SANCO/4802/2001- rev. 2 (May 2003) - Aquatic Guidance Document and the Generic Guidance for FOCUS Surface Water Scenarios, version 1.4, May 2015.

Step 1+2 calculations were conducted with FOCUS SW Steps 1+2 3.2 for Northern and Southern EU. All FOCUS SW Step 3 scenarios were simulated using the program FOCUS SWASH 5.3²⁷ to create the

²⁷ 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, 245 pp

necessary input data for FOCUS MACRO 5.5.4, FOCUS PRZM 4.3.1, SPIN 3.3 and TOXSWA 5.5.3., have been released.

The PEC calculations for zoxamide and its relevant metabolites were in general based on EU concluded endpoints. However, there was a single exception with regard to a geometric mean (n=32) foliar half-life of 3.9 d for zoxamide based on residues data recently evaluated by Klein & Mendel-Kreusel (2020; re-report no. GOW1120-1). According to EFSA (2015)²⁸ and EFSA (2017)²⁹ it is considered acceptable to override the default foliar DT₅₀ of 10 d by experimentally derived substance-specific data from different plants, investigated under a range of relevant conditions. This substance specific foliar DT₅₀ value was additionally considered for refined FOCUS SW calculations. Beside PEC_{actual} values, PEC_{twa} values were estimated as far as necessary for the aqua-toxicological risk assessment. Both single and multiple applications were taken into account.

Step 4 calculations were carried out as far as applicable with the program SWAN 5, which was developed by members of the FOCUS SW expert group, for the implementation of buffer zones and drift mitigation measures. Besides, drift-reducing measures (i.e. buffer zones and drift reducing equipment for the reduction classes 50%, 75% and 90%, respectively) were considered.

Table 8.9-1: Runoff reduction based on vegetated buffer distances

Vegetated Buffer width (m)	5 ^a	10 ^b	15 ^c	20 ^b
Reduction of run-off water	25	60	70	80
Reduction of pesticide in run-off	25	60	70	80
Reduction of soil erosion	50	85	90	95
Reduction of pesticide in eroded soil	50	85	90	95

a Exposit 3.0 b FOCUS (2007), c National specific requirements of e.g. Austria

Although no guidance is given by FOCUS for buffer strips less than 10 m, a reduction in runoff in the water phase of 25% was implemented for a 5 m buffer, together with a reduction in the sediment phase of 50%. This is considered to be a realistic reduction factor based on the FOCUS recommendations and is more conservative than the reduction factor of 40% for a 5 m vegetative buffer strip, which is recommended by the EXPOSIT model used in Germany. Also, no guidance is given by FOCUS for buffer strips of 15 m. Here, the recommendations of e.g. the Austrian authorities were followed with 70% and 90% reduction for the water and the sediment phase.

According to the most recent version of EVA 3 (rev. 2h of 20.09.2017) the vapour pressure of zoxamide of $1.3 \cdot 10^{-5}$ Pa at 25 °C can be transferred to $6.76 \cdot 10^{-6}$ Pa at 20 °C. This is below the trigger of $1.0 \cdot 10^{-5}$ Pa at 20 °C. Therefore, the active substance is not regarded as volatile, and the deposition of volatilised zoxamide was not included in Step 4 calculations.

For all calculations the endpoints established during the EU-review of the active substance data and/or justified in chapter 8.9.1 were taken into account.

²⁸ EFSA (2015): Guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2015;13(4):4093

²⁹ EFSA (2017): Guidance for predicting environmental concentrations in soil. EFSA Journal 2017;15(10):4982

8.9.1 Justification for new endpoints

Zoxamide

Most of the input parameters are in agreement with current EU evaluation results. Please refer to the information provided in the EFSA (2017).

The study of Derz (2020) with [¹⁴C]-RH-24549 as test item investigated further the formation fraction of RH-141455 and the degradation behaviour of RH-24549 and RH-141455. As a result, an arithmetic mean formation fraction of 0.504 (n=4) was found for the transformation of RH-24549 to RH-141455 together with an overall geometric mean DegT₅₀ value of 7.48 days (n=7) for RH-141455 and an overall geometric mean DegT₅₀ value of 6.84 days (n=7) for RH-24549 and used for surface water simulations.

Furthermore, in EFSA (2017) arithmetic mean K_{foc} values are suggested as input values for all substances. However, the respective geometric mean values are used according to current EFSA guidelines (EFSA 2014)³⁰.

Finally, a geometric mean (n=32) foliar half-life of 3.9 d for zoxamide based on residues data for different leafy plants derived from supervised open field and indoor residues trials recently evaluated by Klein & Mendel-Kreusel (2020; report no. GOW1120-1)³¹ have been taken into account.

Cymoxanil

No new endpoints were used for PEC_{sw} calculations of cymoxanil and its metabolites, with the exception of metabolite IN-KQ960 for which the new DT₅₀ and K_{oc} values discussed under points 8.3.1 and 8.5.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

8.9.2.1 Zoxamide and its metabolites

In the following table the input values used for PEC_{sw} calculations for zoxamide and its metabolites are summarised. For refinement, FOCUS SW Step 4 calculations with the reduced max. dose in grapes authorised in southern EU zone countries are included in blue for completeness.

Table 8.9-2: Input parameters related to application for PEC_{SW/SED} calculations

CYMOXANIL 33% + ZOXAMIDE 33% WG		
Use No.	1-12	13-16
Crop (application stage)	potato	grape
Application rate (kg as/ha)	148.5 (zoxamide)	148.5 (zoxamide) 132 (zoxamide)
Number of applications/interval (d)	3/7	3/7
Application window Step 1&2	March to May June - September	March to May June - September
Crop cover	Minimum (early) Full canopy (late)	Minimum (early) Full canopy (late)
Application method	ground spray	air blast

³⁰ EFSA (2014): EFSA 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

³¹ Klein, J. and Mendel-Kreusel, R. (2020): Residue dissipation of Zoxamide on/in plants, Report No. GOW1120-1

Table 8.9-3: FOCUS Step 3 Scenario related input parameters for PEC_{sw/sed} calculations for the application of CYMOXANIL 33% + ZOXAMIDE 33% WG

◦ The late application dates in October/November (valid for southern EU / Greek conditions) are not relevant for the central zone and the here intended GAP use on potatoes with an application timing April to September; they are therefore not considered further.

[illegible]

Compound	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	RH-139432	Value in accordance to EU endpoint y/n/ Reference°
coefficient in water (m ² /d)	for Step 1+2/ 4.3 x 10 ⁻⁵ for Step 3+4	for Step 1+2	for Step 1+2	for Step 1+2	for Step 1+2	for Step 1+2	
Diffusion coefficient in air (m ² /d)	not required for Step 1+2/ 0.43 for Step 3+4	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
K _{foc} (mL/g)	1179 (geometric mean, n = 4)	593 (geometric, n = 3)	90.55 (worst case, n=3)	68 (geometric, n = 3)	2.8 (geometric, n = 3)	10 ⁺	n, geometric means were used
K _{om} (mL/g)	684 (geometric mean, n=4)	344 (geometric mean, n=3)	52.5 (worst-case, n=3)	39 (geometric mean, n=3)	1.6 (geometric mean, n=3)	5.77 ⁺	n, geometric means were used
Freundlich Exponent 1/n	0.970 (arithmetic mean, n=4)	--0.9** (default)	0.811 (arithmetic mean, n=3)	0.892 (arithmetic mean, n=3)	1.0 [#]	0.9 (default)	y (EFSA, 2017)
Half life on crop canopy (d)	not required for Step 1+2/ 10 (Step 3/4)	--	--	--	--	--	default Tier 1
Half life on crop canopy (d) - Refinement	not required for Step 1+2/ 3.9 (Step 3/4) ^{##}	--	--	--	--	--	n Tier 2
Plant Uptake	not required for Step 1+2/ 0 (Step 3/4)*	--	--	--	--	--	y (EFSA, 2017)
Wash-off factor from crop for PRZM and MACRO (1/m)	50	-	-	-	-	-	default
DT _{50,soil} (d)	5.5 (geometric mean, n=6)	5.2 (geometric mean, n=5)	6.84 (geometric mean, n=7, including Derz 2020)	10.8 (geometric mean, n=4)	19.6 (geometric mean, n=4)	1000 ⁺	y EFSA (2017)
DT _{50,soil} (d) - Refined	5.5 (geometric mean, n=6)	5.2 (geometric mean, n=5)	6.84 (geometric mean, n=7, including Derz 2020)	10.8 (geometric mean, n=4)	7.48 (geometric mean, n=7, including Derz 2020)	1000 ⁺	partly y EFSA (2017)
DT _{50,water} (d)	6.4/1000 (Step 1/2) 1000 (Step 3/4)**	237	1000 ⁺	1000 ⁺	1000 ⁺	1000 ⁺	y (EFSA, 2017)
DT _{50,sed} (d)	1000/6.4 (Step 1/2) 6.4 (Step 3/4)**	237	1000 ⁺	1000 ⁺	1000 ⁺	1000 ⁺	y (EFSA, 2017)
DT _{50,whole system} (d)	6.4 d (arithmetic mean, n=2)	237 (arithmetic mean, n=2)	1000 ⁺	1000 ⁺	1000 ⁺	1000 ⁺	y (EFSA, 2017)
Maximum occurrence	--	Soil: 15.1 Total	Soil: 33.8 Surface	Soil: 15 Surface	Soil: 8.4 Surface	Soil: 4.9 Surface	y (EFSA, 2017)

Compound	Zoxamide	RH-127450	RH-24549	RH-163353	RH-141455	RH-139432	Value in accordance to EU endpoint y/n/ Reference ^o
(% molar basis with respect to the parent, Step 1/2)		system: 39.3	water: 5	water: 20.6	water: 2.1	water: 21.4 ⁺⁺	

^o EFSA (2017): EFSA request (Ref. JT/CDL/ml (2017)–out-16903515)

* worst-case

** the combination DegT₅₀ in sediment = 6.4 d and DegT₅₀ 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 (DegT₅₀ of 6.4 days in water, DegT₅₀ of 1000 days in sediment) was therefore not considered further.

+ worst-case default (in the absence of measured values)

++ 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.

default (worst-case) 1/n value of 1.0 assumed for modelling

Klein, J. and Mendel-Kreusel, R. (2020): Residue dissipation of Zoxamide on/in plants, Report No. GOW1120-1

PEC_{sw/sed}

Results of FOCUS SW Step 1/2, Step 3 and Step 4 PEC_{sw/sed} calculations are presented. Selected input and output files are given in Appendix 3 of this document. All input- and output-files of the calculations are available and have been included in the submission.

Steps 1, 2 and 3

In the following tables PEC SW Step 1-3 results are presented for zoxamide in potatoes. The relevant step 3 scenarios are D3, D4, D6, R1, R2, and R3.

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for zoxamide following single and multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes **early⁺**

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	21 d-PEC _{sw, twa} (µg/L)	21 d-PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
Step 1	---	61.834		23.465		680.721	
Step 2							
Northern Europe	March-May	3.6688	2.4095	1.4079	0.9184	41.1398	26.6933
Southern Europe	March-May	6.8016	4.3858	2.6448	1.6987	78.0752	49.9939
Step 3 Foliar DT50 10 days							
D3	Ditch	0.565	0.778	0.057	0.039	0.303	0.369
D4	Pond	0.058	0.031	0.048	0.026	0.125	0.063
D4	Stream	0.454	0.607	0.003	0.001	0.019	0.018
D6 1st	Ditch	0.563	0.769	0.028	0.017	0.218	0.204
D6 2nd	Ditch	0.559	0.763	0.021	0.011	0.153	0.141
R1	Pond	0.103	0.065	0.088	0.055	0.231	0.146
R1	Stream	0.792	0.599	0.039	0.029	0.916	0.748

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	21 d- PEC _{sw, twa} (µg/L)	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
R2	Stream	0.524	0.712	0.029	0.008	0.445	0.106
R3	Stream	0.853	0.759	0.058	0.013	0.440	0.166
Step 3 Foliar DT50 3.9 days							
D3	Ditch	0.565 0.778*	0.778	0.057	0.039	0.303	0.369
D4	Pond	0.058 0.031*	0.031	0.048	0.026	0.125	0.063
D4	Stream	0.454 0.608*	0.607	0.003	0.001	0.019	0.018
D6 1st	Ditch	0.563 0.770*	0.769	0.028	0.017	0.218	0.204
D6 2nd	Ditch	0.559 0.764*	0.763	0.021	0.011	0.153	0.141
R1	Pond	0.087 0.052*	0.052	0.074	0.044	0.196	0.118
R1	Stream	0.534* 0.540*	0.539	0.029	0.021	0.617	0.505
R2	Stream	0.524 0.712*	0.712	0.023	0.007	0.341	0.080
R3	Stream	0.688* 0.760*	0.759	0.050	0.013	0.361	0.166

+ if not expressed differently: drift induced peaks

* single application

° run-off/drainage induced peak

Evaluator's Comments:	In the Table 8.9-5 PEC _{sw} values for zoxamide in scenarios R1 stream and R3 stream are for multiple applications. The PEC _{sw} values for single application was added by evaluator.
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Table 8.9-6: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for zoxamide following single and multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes late⁺

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	21 d- PEC _{sw, twa} (µg/L)	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
Step 1	---	61.834		23.465		680.721	
Step 2							
Northern Europe	June - September	1.6417	1.3657	0.6075	0.5317	17.2405	11.6165
Southern Europe	June - September	2.1946	1.4795	0.8258	0.5512	23.7585	15.7284
Step 3 Foliar DT50 10.0 days							
D3	Ditch	0.566	0.778	0.067	0.041	0.331	0.378

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	21 d- PEC _{sw, twa} (µg/L)	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
D4	Pond	0.057	0.031	0.049	0.026	0.152	0.070
D4	Stream	0.477	0.585	0.004	0.001	0.031	0.014
D6 1 st	Ditch	0.562	0.773	0.033	0.022	0.184	0.247
D6 2 nd	Ditch^	0.716	0.778	0.103	0.043	0.444	0.393
R1	Pond	0.051	0.031	0.043	0.026	0.118	0.062
R1	Stream	0.390	0.535	0.006	0.004	0.058	0.060
R2	Stream	0.523	0.712	0.020	0.011	0.736	0.132
R3	Stream	0.708	0.761	0.108	0.043	1.102	0.727
Step 3 Foliar DT50 3.9 days							
D3	Ditch	0.566	0.778	0.067	0.041	0.331	0.378
D4	Pond	0.057	0.031	0.049	0.026	0.152	0.070
D4	Stream	0.477	0.585	0.004	0.001	0.031	0.014
D6 1 st	Ditch	0.562	0.773	0.033	0.022	0.184	0.247
D6 2 nd	Ditch	0.568	0.778	0.103	0.043	0.444	0.393
R1	Pond	0.051	0.031	0.043	0.026	0.118	0.062
R1	Stream	0.390	0.535	0.006	0.004	0.058	0.060
R2	Stream	0.523	0.712	0.016	0.009	0.370	0.102
R3	Stream	0.552	0.761	0.075	0.030	0.668	0.460

+ if not expressed differently: drift induced peaks

* single application

° run-off/drainage induced peak

^ not relevant for the central zone/the here intended GAP uses

Evaluator's Comments:	In the Table 8.9-5 PEC _{sw} values for zoxamide in scenarios R1 stream and R3 stream are for multiple applications. The PEC _{sw} values for single application was added by evaluator.
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In the following tables PEC SW Step 1-3 results are presented for zoxamide in vines, early and late. The relevant step 3 scenarios are D6, R1, R2, R3, and R4.

Table 8.9-7: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for zoxamide following single and multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vines, early⁺

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	21 d- PEC _{sw,twa} (µg/L)	21 d- PEC _{sw,twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
Step 1	---	61.7452		23.4502		680.7212	
Step 2							
Northern Europe	March-May	2.886	1.819	1.088	0.686	31.361	19.766

- + if not expressed differently: drift induced peaks
- * single application
- o run-off/drainage induced peak

Evaluator's Comments:	In the Table 8.9-7 PECsw values for zoxamide in scenarios R4 stream is for multiple applications. The PECsw values for single application was added by evaluator.
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Table 8.9-8: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sd} for zoxamide following single and multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vines late⁺

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Max PEC_{csw} (µg/L)*	21 d- PEC_{sw,twa} (µg/L)	21 d- PEC_{sw,twa} (µg/L)*	Max PEC_{sed} (µg/kg)	Max PEC_{csed} (µg/kg)*
Step 1	---	69.659		24.779		680.721	
Step 2							
Northern Europe	June - September	4.562	3.974	1.624	1.114	31.711	20.837
Southern Europe	June - September	4.562	3.974	1.914	1.297	40.401	26.320
Step 3 Foliar DT50 10 days							

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	21 d- PEC _{sw, twa} (µg/L)	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
D6	Ditch	3.156	2.546	1.856	0.846	4.482	3.117
R1	Pond	0.192	0.091	0.165	0.075	0.570	0.216
R1	Stream	1.592	1.868	0.032	0.019	0.283	0.268
R2	Stream	2.134	2.503	0.022	0.013	0.184	0.191
R3	Stream	2.244	2.632	0.192	0.074	2.235	0.594
R4	Stream	2.344	1.867	0.154	0.045	1.452	0.355
Step 3 Foliar DT50 3.9 days							
D6	Ditch	3.156 2.546*	2.546	1.856	0.846	4.482	3.117
R1	Pond	0.192 0.091*	0.091	0.165	0.075	0.570	0.216
R1	Stream	1.592 1.868*	1.868	0.032	0.019	0.283	0.268
R2	Stream	2.134 2.503*	2.503	0.022	0.013	0.184	0.191
R3	Stream	2.244 2.635*	2.632	0.140	0.056	1.423	0.594
R4	Stream	1.591 1.869*	1.867	0.111	0.028	0.914	0.264

+ if not expressed differently: drift induced peaks

* single application

° run-off/drainage induced peak

Evaluator's Comments:	In the Table 8.9-8 PEC _{sw} values for single application was added by evaluator.
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Step 4

The results of the step 4 calculations are summarised in the following tables, taking into account runoff and drift reducing measures as far as applicable. Simulation in vines were performed also considering the reduced dose of 3*132 g/ha (instead of 3*148.5 g/ha).

Table 8.9-9: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to potatoes early at Step 4 (Tier 1. Foliar half-life 10 d)

PECSW [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.565					0.182	0.095	0.065	0.049
50 %		0.283					0.091	0.048	0.032	0.024
75 %		0.141					0.045	0.024	0.016	0.012
90 %		0.057					0.018	0.010	0.006	0.005
None	D4 pond	0.058					0.052	0.037	0.029	0.024
50 %		0.029					0.026	0.018	0.015	0.012
75 %		0.014					0.013	0.009	0.007	0.006
90 %		0.006					0.005	0.004	0.003	0.002
None	D4 stream	0.454					0.188	0.099	0.067	0.051
50 %		0.227					0.094	0.049	0.033	0.025
75 %		0.114					0.047	0.025	0.017	0.013
90 %		0.045					0.019	0.010	0.007	0.005
None	D6 ditch 1st	0.563					0.181	0.095	0.064	0.049
50 %		0.282					0.090	0.047	0.032	0.024
75 %		0.141					0.045	0.024	0.016	0.012
90 %		0.056					0.018	0.009	0.006	0.005
None	D6 ditch 2nd	0.559					0.179	0.094	0.064	0.048
50 %		0.279					0.090	0.047	0.032	0.024
75 %		0.140					0.045	0.024	0.016	0.012
90 %		0.056					0.018	0.009	0.008	0.008
None	R1 pond	0.103					0.085	0.054	0.042	0.033
50 %		0.076					0.061	0.037	0.028	0.021
75 %		0.062					0.049	0.028	0.021	0.015
90 %		0.055					0.042	0.023	0.017	0.012

PECSW [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.792*					0.625*	0.360*	0.276*	0.189*
50 %		0.792*					0.625*	0.360*	0.276*	0.189*
75 %		0.792*					0.625*	0.360*	0.276*	0.189*
90 %		0.792*					0.625*	0.360*	0.276*	0.189*
None	R2 stream	0.523					0.371*	0.211*	0.161*	0.110*
50 %		0.473*					0.371*	0.211*	0.161*	0.110*
75 %		0.473*					0.371*	0.211*	0.161*	0.110*
90 %		0.473*					0.371*	0.211*	0.161*	0.110*
None	R3 stream	0.853*					0.673*	0.387*	0.297*	0.203*
50 %		0.853*					0.673*	0.387*	0.297*	0.203*
75 %		0.853*					0.673*	0.387*	0.297*	0.203*
90 %		0.853*					0.673*	0.387*	0.297*	0.203*

* run-off/drainage induced

Table 8.9-10: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes early at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.057					0.018	0.010	0.007	0.005
50 %		0.029					0.009	0.005	0.003	0.002
75 %		0.014					0.005	0.002	0.002	0.001
90 %		0.006					0.002	0.001	0.001	<0.001
None	D4 pond	0.048					0.043	0.031	0.024	0.020
50 %		0.024					0.021	0.015	0.012	0.010
75 %		0.012					0.011	0.008	0.006	0.005
90 %		0.005					0.004	0.003	0.002	0.002
None	D4 stream	0.003					0.001	0.001	<0.001	<0.001
50 %		0.001					0.001	<0.001	<0.001	<0.001
75 %		0.001					<0.001	<0.001	<0.001	<0.001
90 %		<0.001					<0.001	<0.001	<0.001	<0.001
None	D6 ditch 1st	0.028					0.009	0.005	0.003	0.002
50 %		0.014					0.005	0.002	0.002	0.001
75 %		0.007					0.002	0.001	0.001	0.001
90 %		0.003					0.001	<0.001	<0.001	<0.001
None	D6 ditch 2nd	0.021					0.007	0.004	0.002	0.002
50 %		0.011					0.003	0.002	0.001	0.001
75 %		0.005					0.002	0.001	0.001	<0.001
90 %		0.002					0.001	<0.001	<0.001	<0.001
None	R1 pond	0.088					0.072	0.046	0.036	0.028
50 %		0.065					0.052	0.032	0.024	0.018
75 %		0.054					0.042	0.024	0.019	0.013
90 %		0.048					0.036	0.020	0.015	0.011

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.039					0.030	0.017	0.013	0.009
50 %		0.038					0.029	0.016	0.013	0.009
75 %		0.037					0.028	0.016	0.012	0.008
90 %		0.036					0.028	0.016	0.012	0.008
None	R2 stream	0.029					0.021	0.012	0.009	0.006
50 %		0.027					0.020	0.011	0.009	0.006
75 %		0.026					0.020	0.011	0.008	0.006
90 %		0.025					0.019	0.011	0.008	0.006
None	R3 stream	0.058					0.039	0.022	0.016	0.011
50 %		0.049					0.035	0.020	0.015	0.010
75 %		0.044					0.033	0.019	0.014	0.010
90 %		0.041					0.032	0.018	0.014	0.009

Table 8.9-11: Global maximum PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to potatoes early at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.778					0.255	0.135	0.092	0.070
50 %		0.389					0.127	0.068	0.046	0.035
75 %		0.194					0.064	0.034	0.023	0.018
90 %		0.078					0.025	0.014	0.009	0.007
None	D4 pond	0.031					0.028	0.020	0.016	0.013
50 %		0.016					0.014	0.010	0.008	0.007
75 %		0.008					0.007	0.005	0.004	0.003
90 %		0.003					0.003	0.002	0.002	0.001
None	D4 stream	0.607					0.256	0.136	0.093	0.070
50 %		0.304					0.128	0.068	0.046	0.035
75 %		0.152					0.064	0.034	0.023	0.018
90 %		0.061					0.026	0.014	0.009	0.007
None	D6 ditch 1st	0.769					0.252	0.134	0.091	0.069
50 %		0.385					0.126	0.067	0.046	0.035
75 %		0.192					0.063	0.033	0.023	0.017
90 %		0.077					0.025	0.013	0.009	0.007
None	D6 ditch 2nd	0.763					0.250	0.133	0.091	0.069
50 %		0.382					0.125	0.066	0.045	0.034
75 %		0.191					0.063	0.033	0.023	0.017
90 %		0.076					0.025	0.013	0.009	0.007
None	R1 pond	0.065					0.053	0.033	0.025	0.019
50 %		0.052					0.041	0.024	0.018	0.013
75 %		0.045					0.035	0.020	0.015	0.011
90 %		0.042					0.032	0.017	0.013	0.009

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.599*					0.473*	0.272*	0.209*	0.143*
50 %		0.599*					0.473*	0.272*	0.209*	0.143*
75 %		0.599*					0.473*	0.272*	0.209*	0.143*
90 %		0.599*					0.473*	0.272*	0.209*	0.143*
None	R2 stream	0.712					0.300	0.159	0.109	0.083
50 %		0.356					0.150	0.080	0.056*	0.041
75 %		0.178					0.129*	0.073*	0.056*	0.038*
90 %		0.164					0.129*	0.073*	0.056*	0.038*
None	R3 stream	0.759					0.320	0.170	0.116	0.088
50 %		0.380					0.160	0.085	0.058	0.044
75 %		0.190					0.115*	0.066*	0.051*	0.035*
90 %		0.146					0.115*	0.066*	0.051*	0.035*

* run-off/drainage induced

Table 8.9-12: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes early at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.039					0.013	0.007	0.005	0.003
50 %		0.019					0.006	0.003	0.002	0.002
75 %		0.010					0.003	0.002	0.001	0.001
90 %		0.004					0.001	0.001	<0.001	<0.001
None	D4 pond	0.026					0.023	0.017	0.013	0.011
50 %		0.013					0.011	0.008	0.007	0.006
75 %		0.006					0.006	0.004	0.003	0.003
90 %		0.003					0.002	0.002	0.001	0.001
None	D4 stream	0.001					<0.001	<0.001	<0.001	<0.001
50 %		0.001					<0.001	<0.001	<0.001	<0.001
75 %		<0.001					<0.001	<0.001	<0.001	<0.001
90 %		<0.001					<0.001	<0.001	<0.001	<0.001
None	D6 ditch 1st	0.017					0.006	0.003	0.002	0.002
50 %		0.008					0.003	0.001	0.001	0.001
75 %		0.004					0.001	0.001	0.001	<0.001
90 %		0.002					0.001	<0.001	<0.001	<0.001
None	D6 ditch 2nd	0.011					0.004	0.002	0.001	0.001
50 %		0.006					0.002	0.001	0.001	<0.001
75 %		0.003					0.001	<0.001	<0.001	<0.001
90 %		0.001					<0.001	<0.001	<0.001	<0.001
None	R1 pond	0.055					0.044	0.028	0.021	0.016
50 %		0.044					0.034	0.020	0.016	0.011
75 %		0.038					0.029	0.017	0.013	0.009
90 %		0.035					0.026	0.014	0.011	0.007

PEC _{SW} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.029					0.021	0.012	0.009	0.006
50 %		0.026					0.020	0.011	0.009	0.006
75 %		0.025					0.019	0.011	0.008	0.006
90 %		0.024					0.019	0.011	0.008	0.006
None	R2 stream	0.008					0.005	0.003	0.002	0.002
50 %		0.007					0.005	0.003	0.002	0.002
75 %		0.007					0.005	0.003	0.002	0.002
90 %		0.007					0.005	0.003	0.002	0.002
None	R3 stream	0.013					0.006	0.003	0.002	0.002
50 %		0.007					0.005	0.003	0.002	0.002
75 %		0.007					0.005	0.003	0.002	0.002
90 %		0.007					0.005	0.003	0.002	0.002

Table 8.9-13: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes late at Step 4 (Tier 1. Foliar half-life 10 d)

PECSW [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.566					0.182	0.095	0.065	0.049
50 %		0.283					0.091	0.048	0.032	0.024
75 %		0.142					0.045	0.024	0.016	0.012
90 %		0.057					0.018	0.010	0.006	0.005
None	D4 pond	0.057					0.051	0.036	0.029	0.024
50 %		0.029					0.025	0.018	0.014	0.012
75 %		0.014					0.013	0.009	0.007	0.006
90 %		0.006					0.005	0.005	0.004	0.004
None	D4 stream	0.477					0.198	0.104	0.070	0.053
50 %		0.238					0.099	0.052	0.035	0.027
75 %		0.119					0.049	0.026	0.018	0.018
90 %		0.048					0.020	0.018	0.018	0.018
None	D6 ditch 1st	0.562					0.180	0.095	0.064	0.049
50 %		0.281					0.090	0.047	0.032	0.024
75 %		0.140					0.045	0.024	0.016	0.012
90 %		0.056					0.018	0.009	0.006	0.005
None	D6 ditch 2 nd Λ	0.716 [§]					0.716 [§]	0.716 [§]	0.716 [§]	0.716 [§]
50 %		0.716 [§]					0.716 [§]	0.716 [§]	0.716 [§]	0.716 [§]
75 %		0.716 [§]					0.716 [§]	0.716 [§]	0.716 [§]	0.716 [§]
90 %		0.716 [§]					0.716 [§]	0.716 [§]	0.716 [§]	0.716 [§]
None	R1 pond	0.051					0.045	0.032	0.025	0.021
50 %		0.025					0.022	0.016	0.013	0.011
75 %		0.013					0.011	0.008	0.006	0.005
90 %		0.007					0.005	0.003	0.003	0.002

PECSW [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.390					0.162	0.085	0.058	0.044
50 %		0.195					0.081	0.044*	0.033*	0.023*
75 %		0.098*					0.077*	0.044*	0.033*	0.023*
90 %		0.098*					0.077*	0.044*	0.033*	0.023*
None	R2 stream	0.523					0.266*	0.151*	0.116*	0.079*
50 %		0.339*					0.266*	0.151*	0.116*	0.079*
75 %		0.339*					0.266*	0.151*	0.116*	0.079*
90 %		0.339*					0.266*	0.151*	0.116*	0.079*
None	R3 stream	0.708*					0.560*	0.323*	0.248*	0.169*
50 %		0.708*					0.560*	0.323*	0.248*	0.169*
75 %		0.708*					0.560*	0.323*	0.248*	0.169*
90 %		0.708*					0.560*	0.323*	0.248*	0.169*

* run-off/drainage induced ^not relevant for the central zone

Table 8.9-14: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes late at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.067					0.021	0.011	0.008	0.006
50 %		0.033					0.011	0.006	0.004	0.003
75 %		0.017					0.005	0.003	0.002	0.001
90 %		0.007					0.002	0.001	0.001	0.001
None	D4 pond	0.049					0.044	0.031	0.025	0.021
50 %		0.025					0.022	0.016	0.012	0.010
75 %		0.012					0.011	0.008	0.006	0.005
90 %		0.005					0.004	0.004	0.004	0.003
None	D4 stream	0.004					0.002	0.001	0.001	0.001
50 %		0.002					0.001	0.001	0.001	0.001
75 %		0.001					0.001	0.001	0.001	0.001
90 %		0.001					0.001	0.001	0.001	0.001
None	D6 ditch 1st	0.033					0.010	0.005	0.004	0.003
50 %		0.016					0.005	0.003	0.002	0.001
75 %		0.008					0.003	0.001	0.001	0.001
90 %		0.003					0.001	0.001	<0.001	<0.001
None	D6 ditch 2nd	0.103					0.033	0.020	0.016	0.014
50 %		0.051					0.019	0.014	0.012	0.011
75 %		0.026					0.014	0.011	0.011	0.010
90 %		0.015					0.011	0.010	0.010	0.010
None	R1 pond	0.043					0.038	0.027	0.021	0.018
50 %		0.021					0.019	0.014	0.011	0.009
75 %		0.011					0.009	0.007	0.005	0.004
90 %		0.006					0.005	0.003	0.002	0.002

PEC _{SW} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.006					0.003	0.002	0.001	0.001
50 %		0.003					0.003	0.002	0.001	0.001
75 %		0.003					0.003	0.002	0.001	0.001
90 %		0.003					0.003	0.002	0.001	0.001
None	R2 stream	0.020					0.014	0.008	0.006	0.004
50 %		0.018					0.013	0.007	0.005	0.004
75 %		0.016					0.012	0.007	0.005	0.004
90 %		0.016					0.012	0.007	0.005	0.004
None	R3 stream	0.108					0.074	0.042	0.032	0.022
50 %		0.093					0.068	0.039	0.030	0.020
75 %		0.086					0.065	0.037	0.029	0.020
90 %		0.081					0.063	0.037	0.028	0.019

^anot relevant for the central zone

Table 8.9-15: Global maximum PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes late at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.778					0.255	0.135	0.092	0.070
50 %		0.389					0.128	0.068	0.046	0.035
75 %		0.195					0.064	0.034	0.023	0.018
90 %		0.078					0.026	0.014	0.009	0.007
None	D4 pond	0.031					0.028	0.020	0.016	0.013
50 %		0.016					0.014	0.010	0.008	0.007
75 %		0.008					0.007	0.005	0.004	0.003
90 %		0.003					0.003	0.002	0.002	0.001
None	D4 stream	0.585					0.246	0.131	0.089	0.068
50 %		0.292					0.123	0.065	0.045	0.034
75 %		0.146					0.062	0.033	0.022	0.017
90 %		0.058					0.025	0.013	0.009	0.007
None	D6 ditch 1st	0.773					0.253	0.134	0.092	0.070
50 %		0.387					0.127	0.067	0.046	0.035
75 %		0.193					0.063	0.034	0.023	0.017
90 %		0.077					0.025	0.013	0.009	0.007
None	D6 ditch 2 nd C	0.778					0.255	0.135	0.119 [§]	0.119 [§]
50 %		0.389					0.128	0.119 [§]	0.119 [§]	0.119 [§]
75 %		0.195					0.119 [§]	0.119 [§]	0.119 [§]	0.119 [§]
90 %		0.119 [§]					0.119 [§]	0.119 [§]	0.119 [§]	0.119 [§]
None	R1 pond	0.031					0.028	0.020	0.016	0.013
50 %		0.016					0.014	0.010	0.008	0.007
75 %		0.008					0.007	0.005	0.004	0.003
90 %		0.003					0.003	0.002	0.002	0.001

PEC _{Sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.535					0.225	0.119	0.082	0.062
50 %		0.267					0.113	0.060	0.041	0.031
75 %		0.134					0.056	0.030	0.020	0.016
90 %		0.053					0.023	0.012	0.008	0.006
None	R2 stream	0.712					0.300	0.159	0.109	0.083
50 %		0.356					0.160*	0.091*	0.069*	0.047*
75 %		0.204*					0.160*	0.091*	0.069*	0.047*
90 %		0.204*					0.160*	0.091*	0.069*	0.047*
None	R3 stream	0.761					0.407*	0.235*	0.180*	0.123*
50 %		0.515*					0.407*	0.235*	0.180*	0.123*
75 %		0.515*					0.407*	0.235*	0.180*	0.123*
90 %		0.515*					0.407*	0.235*	0.180*	0.123*

* run-off/drainage induced ^not relevant for the central zone / the here intended GAP uses

Table 8.9-16: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes late at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.041					0.013	0.007	0.005	0.004
50 %		0.020					0.007	0.004	0.002	0.002
75 %		0.010					0.003	0.002	0.001	0.001
90 %		0.004					0.001	0.001	<0.001	<0.001
None	D4 pond	0.026					0.023	0.017	0.013	0.011
50 %		0.013					0.012	0.008	0.007	0.006
75 %		0.006					0.006	0.004	0.003	0.003
90 %		0.003					0.002	0.002	0.001	0.001
None	D4 stream	0.001					<0.001	<0.001	<0.001	<0.001
50 %		<0.001					<0.001	<0.001	<0.001	<0.001
75 %		<0.001					<0.001	<0.001	<0.001	<0.001
90 %		<0.001					<0.001	<0.001	<0.001	<0.001
None	D6 ditch 1st	0.022					0.007	0.004	0.003	0.002
50 %		0.011					0.004	0.002	0.001	0.001
75 %		0.006					0.002	0.001	0.001	0.001
90 %		0.002					0.001	<0.001	<0.001	<0.001
None	D6 ditch 2nd ^o	0.043					0.014	0.007	0.005	0.004
50 %		0.021					0.007	0.004	0.003	0.002
75 %		0.011					0.003	0.002	0.002	0.002
90 %		0.004					0.002	0.002	0.002	0.002
None	R1 pond	0.026					0.023	0.017	0.013	0.011
50 %		0.013					0.011	0.008	0.007	0.006
75 %		0.006					0.006	0.004	0.003	0.003
90 %		0.003					0.002	0.002	0.001	0.001

PEC _{SW} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.004					0.002	0.001	0.001	<0.001
50 %		0.002					0.001	<0.001	<0.001	<0.001
75 %		0.001					<0.001	<0.001	<0.001	<0.001
90 %		<0.001					<0.001	<0.001	<0.001	<0.001
None	R2 stream	0.011					0.008	0.004	0.003	0.002
50 %		0.010					0.007	0.004	0.003	0.002
75 %		0.009					0.007	0.004	0.003	0.002
90 %		0.008					0.007	0.004	0.003	0.002
None	R3 stream	0.043					0.029	0.016	0.012	0.009
50 %		0.036					0.026	0.015	0.011	0.008
75 %		0.032					0.024	0.014	0.011	0.007
90 %		0.030					0.024	0.014	0.010	0.007

not relevant for the central zone / the here intended GAP uses

Table 8.9-17: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vine early at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.773						0.145	0.074	0.046
50 %		0.387						0.073	0.037	0.023
75 %		0.193						0.036	0.019	0.011
90 %		0.077						0.015	0.007	0.005
None	R1 pond	0.059						0.036	0.023	0.017
50 %		0.032						0.018	0.012	0.009
75 %		0.020						0.010	0.007	0.005
90 %		0.013						0.006	0.004	0.003
None	R1 stream	0.792*						0.335*	0.253*	0.171*
50 %		0.792*						0.335*	0.253*	0.171*
75 %		0.792*						0.335*	0.253*	0.171*
90 %		0.792*						0.335*	0.253*	0.171*
None	R2 stream	0.743						0.171	0.087	0.054
50 %		0.371						0.086	0.044	0.027
75 %		0.186						0.043	0.022	0.014
90 %		0.074						0.023	0.018	0.012
None	R3 stream	0.784						0.181	0.092	0.057
50 %		0.392						0.090	0.046	0.029
75 %		0.196						0.045	0.023	0.014
90 %		0.078						0.018	0.009	0.006
None	R4 stream	1.410*						0.627*	0.481*	0.328*
50 %		1.410*						0.627*	0.481*	0.328*
75 %		1.410*						0.627*	0.481*	0.328*
90 %		1.410*						0.627*	0.481*	0.328*

* run-off/drainage induced

Table 8.9-18: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vine early at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.176						0.033	0.017	0.010
50 %		0.088						0.017	0.008	0.005
75 %		0.044						0.008	0.004	0.003
90 %		0.018						0.003	0.002	0.001
None	R1 pond	0.055						0.032	0.021	0.015
50 %		0.030						0.017	0.011	0.008
75 %		0.018						0.009	0.006	0.004
90 %		0.011						0.005	0.004	0.003
None	R1 stream	0.033						0.013	0.010	0.007
50 %		0.031						0.013	0.010	0.007
75 %		0.031						0.013	0.010	0.007
90 %		0.030						0.013	0.010	0.006
None	R2 stream	0.009						0.002	0.001	0.001
50 %		0.005						0.001	0.001	0.001
75 %		0.003						0.001	0.001	0.001
90 %		0.003						0.001	0.001	0.001
None	R3 stream	0.023						0.005	0.003	0.002
50 %		0.012						0.003	0.001	0.001
75 %		0.006						0.001	0.001	<0.001
90 %		0.002						0.001	<0.001	<0.001
None	R4 stream	0.116						0.050	0.038	0.026
50 %		0.112						0.049	0.038	0.026
75 %		0.111						0.049	0.037	0.025
90 %		0.110						0.049	0.037	0.025

Table 8.9-19: Global maximum PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vine early at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.829						0.174	0.093	0.059
50 %		0.415						0.087	0.046	0.030
75 %		0.207						0.044	0.023	0.015
90 %		0.083						0.017	0.009	0.006
None	R1 pond	0.029						0.018	0.012	0.009
50 %		0.014						0.009	0.006	0.004
75 %		0.007						0.005	0.003	0.002
90 %		0.003						0.002	0.001	0.001
None	R1 stream	0.611						0.155	0.083	0.053
50 %		0.306						0.078	0.044*	0.030*
75 %		0.153						0.058*	0.044*	0.030*
90 %		0.138						0.058*	0.044*	0.030*
None	R2 stream	0.812						0.206	0.110	0.070
50 %		0.406						0.103	0.055	0.035
75 %		0.203						0.052	0.028	0.018
90 %		0.081						0.021	0.011	0.007
None	R3 stream	0.865						0.220	0.117	0.075
50 %		0.432						0.110	0.059	0.037
75 %		0.216						0.055	0.029	0.019
90 %		0.086						0.022	0.012	0.007
None	R4 stream	0.605						0.231*	0.177*	0.121*
50 %		0.515*						0.231*	0.177*	0.121*
75 %		0.515*						0.231*	0.177*	0.121*
90 %		0.515*						0.231*	0.177*	0.121*

* run-off/drainage induced

Table 8.9-20: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vine early at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.019						0.004	0.002	0.001
50 %		0.009						0.002	0.001	0.001
75 %		0.005						0.001	0.001	<0.001
90 %		0.002						<0.001	<0.001	<0.001
None	R1 pond	0.024						0.015	0.010	0.007
50 %		0.012						0.007	0.005	0.004
75 %		0.006						0.004	0.002	0.002
90 %		0.003						0.001	0.001	0.001
None	R1 stream	0.005						0.002	0.002	0.001
50 %		0.005						0.002	0.002	0.001
75 %		0.005						0.002	0.002	0.001
90 %		0.005						0.002	0.002	0.001
None	R2 stream	0.003						0.001	<0.001	<0.001
50 %		0.002						<0.001	<0.001	<0.001
75 %		0.001						<0.001	<0.001	<0.001
90 %		<0.001						<0.001	<0.001	<0.001
None	R3 stream	0.012						0.003	0.002	0.001
50 %		0.006						0.002	0.001	0.001
75 %		0.003						0.001	<0.001	<0.001
90 %		0.001						<0.001	<0.001	<0.001
None	R4 stream	0.044						0.019	0.014	0.010
50 %		0.042						0.018	0.014	0.009
75 %		0.041						0.018	0.014	0.009
90 %		0.040						0.018	0.014	0.009

* run-off/drainage induced

Table 8.9-21: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vine late at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	3.156						0.677	0.365	0.234
50 %		1.577						0.338	0.182	0.117
75 %		0.788						0.169	0.091	0.058
90 %		0.315						0.067	0.052	0.052
None	R1 pond	0.192						0.122	0.082	0.061
50 %		0.096						0.061	0.041	0.030
75 %		0.048						0.030	0.020	0.015
90 %		0.019						0.012	0.008	0.006
None	R1 stream	1.592						0.413	0.223	0.143
50 %		0.796						0.207	0.111	0.071
75 %		0.398						0.103	0.063	0.043
90 %		0.183						0.082	0.063	0.043
None	R2 stream	2.134						0.554	0.298	0.192
50 %		1.067						0.277	0.149	0.096
75 %		0.533						0.138	0.075	0.048
90 %		0.213						0.055	0.030	0.019
None	R3 stream	2.244						0.582	0.386*	0.264*
50 %		1.122						0.503*	0.386*	0.264*
75 %		1.108*						0.503*	0.386*	0.264*
90 %		1.108*						0.503*	0.386*	0.264*
None	R4 stream	2.344*						1.049*	0.803*	0.546*
50 %		2.344*						1.049*	0.803*	0.546*
75 %		2.344*						1.049*	0.803*	0.546*
90 %		2.344*						1.049*	0.803*	0.546*

* run-off/drainage induced

Table 8.9-22: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vine late at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	1.856						0.397	0.214	0.137
50 %		0.927						0.198	0.107	0.069
75 %		0.463						0.099	0.053	0.034
90 %		0.185						0.040	0.021	0.014
None	R1 pond	0.165						0.105	0.070	0.052
50 %		0.082						0.052	0.035	0.026
75 %		0.041						0.026	0.018	0.013
90 %		0.016						0.010	0.007	0.005
None	R1 stream	0.032						0.008	0.004	0.003
50 %		0.016						0.004	0.002	0.001
75 %		0.008						0.002	0.002	0.001
90 %		0.006						0.002	0.002	0.001
None	R2 stream	0.022						0.006	0.003	0.002
50 %		0.011						0.003	0.002	0.001
75 %		0.005						0.001	0.001	0.001
90 %		0.003						0.001	0.001	0.001
None	R3 stream	0.192						0.076	0.055	0.037
50 %		0.163						0.068	0.051	0.034
75 %		0.148						0.064	0.049	0.033
90 %		0.139						0.062	0.047	0.032
None	R4 stream	0.154						0.060	0.043	0.029
50 %		0.130						0.053	0.039	0.027
75 %		0.118						0.050	0.038	0.026
90 %		0.111						0.048	0.037	0.025

Table 8.9-23: Global maximum PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vine late at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	2.546						0.558	0.303	0.196
50 %		1.273						0.279	0.152	0.098
75 %		0.636						0.139	0.076	0.049
90 %		0.255						0.056	0.030	0.020
None	R1 pond	0.091						0.058	0.039	0.029
50 %		0.045						0.029	0.020	0.015
75 %		0.023						0.014	0.010	0.007
90 %		0.009						0.006	0.004	0.003
None	R1 stream	1.868						0.493	0.268	0.173
50 %		0.934						0.246	0.134	0.086
75 %		0.467						0.123	0.067	0.043
90 %		0.187						0.049	0.027	0.017
None	R2 stream	2.503						0.661	0.359	0.232
50 %		1.251						0.330	0.179	0.116
75 %		0.626						0.165	0.090	0.058
90 %		0.250						0.066	0.036	0.023
None	R3 stream	2.632						0.695	0.377	0.244
50 %		1.316						0.347	0.189	0.122
75 %		0.658						0.174	0.094	0.061
90 %		0.263						0.108	0.083	0.057
None	R4 stream	1.867						0.493	0.268	0.173
50 %		0.934						0.262*	0.200*	0.136*
75 %		0.585*						0.262*	0.200*	0.136*
90 %		0.585*						0.262*	0.200*	0.136*

* run-off/drainage induced

Table 8.9-24: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to vine late at Step 4 (Tier 1. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.846						0.185	0.100	0.065
50 %		0.422						0.092	0.050	0.032
75 %		0.211						0.046	0.025	0.016
90 %		0.084						0.018	0.010	0.006
None	R1 pond	0.075						0.048	0.032	0.024
50 %		0.037						0.024	0.016	0.012
75 %		0.019						0.012	0.008	0.006
90 %		0.007						0.005	0.003	0.002
None	R1 stream	0.019						0.005	0.003	0.002
50 %		0.009						0.002	0.001	0.001
75 %		0.005						0.001	0.001	<0.001
90 %		0.002						<0.001	<0.001	<0.001
None	R2 stream	0.013						0.003	0.002	0.001
50 %		0.006						0.002	0.001	0.001
75 %		0.003						0.001	<0.001	<0.001
90 %		0.001						<0.001	<0.001	<0.001
None	R3 stream	0.074						0.025	0.016	0.011
50 %		0.051						0.019	0.013	0.009
75 %		0.039						0.016	0.011	0.008
90 %		0.032						0.014	0.010	0.007
None	R4 stream	0.045						0.017	0.012	0.008
50 %		0.036						0.014	0.010	0.007
75 %		0.031						0.013	0.010	0.007
90 %		0.028						0.012	0.009	0.006

* run-off/drainage induced

Table 8.9-25: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to potatoes at Step 4 (Tier 2. Foliar half-life 3.9 d)

PECSW [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.565					0.182	0.095	0.065	0.049
50 %		0.283					0.091	0.048	0.032	0.024
75 %		0.141					0.045	0.024	0.016	0.012
90 %		0.057					0.018	0.010	0.006	0.005
None	D4 pond	0.058					0.052	0.037	0.029	0.024
50 %		0.029					0.026	0.018	0.015	0.012
75 %		0.014					0.013	0.009	0.007	0.006
90 %		0.006					0.005	0.004	0.003	0.002
None	D4 stream	0.454					0.188	0.099	0.067	0.051
50 %		0.227					0.094	0.049	0.033	0.025
75 %		0.114					0.047	0.025	0.017	0.013
90 %		0.045					0.019	0.010	0.007	0.005
None	D6 ditch 1st	0.563					0.181	0.095	0.064	0.049
50 %		0.282					0.090	0.047	0.032	0.024
75 %		0.141					0.045	0.024	0.016	0.012
90 %		0.056					0.018	0.009	0.006	0.005
None	D6 ditch 2nd	0.559					0.179	0.094	0.064	0.048
50 %		0.279					0.090	0.047	0.032	0.024
75 %		0.140					0.045	0.024	0.016	0.012
90 %		0.056					0.018	0.009	0.006	0.005
None	R1 pond	0.087					0.073	0.048	0.037	0.029
50 %		0.060					0.049	0.030	0.024	0.018
75 %		0.046					0.037	0.022	0.017	0.012
90 %		0.038					0.030	0.017	0.013	0.009

PECSW [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.534*					0.422*	0.243*	0.186*	0.127*
50 %		0.534*					0.422*	0.243*	0.186*	0.127*
75 %		0.534*					0.422*	0.243*	0.186*	0.127*
90 %		0.534*					0.422*	0.243*	0.186*	0.127*
None	R2 stream	0.523					0.275*	0.156*	0.119*	0.081*
50 %		0.350*					0.275*	0.156*	0.119*	0.081*
75 %		0.350*					0.275*	0.156*	0.119*	0.081*
90 %		0.350*					0.275*	0.156*	0.119*	0.081*
None	R3 stream	0.688*					0.543*	0.312*	0.239*	0.163*
50 %		0.688*					0.543*	0.312*	0.239*	0.163*
75 %		0.688*					0.543*	0.312*	0.239*	0.163*
90 %		0.688*					0.543*	0.312*	0.239*	0.163*

* run-off/drainage induced

Table 8.9-26: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to potatoes at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.057					0.018	0.010	0.007	0.005
50 %		0.029					0.009	0.005	0.003	0.002
75 %		0.014					0.005	0.002	0.002	0.001
90 %		0.006					0.002	0.001	0.001	0.000
None	D4 pond	0.048					0.043	0.031	0.024	0.020
50 %		0.024					0.021	0.015	0.012	0.010
75 %		0.012					0.011	0.008	0.006	0.005
90 %		0.005					0.004	0.003	0.002	0.002
None	D4 stream	0.003					0.001	0.001	0.000	0.000
50 %		0.001					0.001	0.000	0.000	0.000
75 %		0.001					0.000	0.000	0.000	0.000
90 %		0.000					0.000	0.000	0.000	0.000
None	D6 ditch 1st	0.028					0.009	0.005	0.003	0.002
50 %		0.014					0.005	0.002	0.002	0.001
75 %		0.007					0.002	0.001	0.001	0.001
90 %		0.003					0.001	0.000	0.000	0.000
None	D6 ditch 2nd	0.021					0.007	0.004	0.002	0.002
50 %		0.011					0.003	0.002	0.001	0.001
75 %		0.005					0.002	0.001	0.001	0.000
90 %		0.002					0.001	0.000	0.000	0.000
None	R1 pond	0.074					0.062	0.040	0.031	0.025
50 %		0.051					0.042	0.026	0.020	0.015
75 %		0.040					0.032	0.019	0.014	0.011
90 %		0.034					0.026	0.015	0.011	0.008

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.029					0.021	0.012	0.009	0.006
50 %		0.027					0.021	0.012	0.009	0.006
75 %		0.026					0.020	0.011	0.009	0.006
90 %		0.026					0.020	0.011	0.009	0.006
None	R2 stream	0.023					0.016	0.009	0.007	0.005
50 %		0.021					0.015	0.009	0.007	0.005
75 %		0.020					0.015	0.008	0.006	0.004
90 %		0.019					0.015	0.008	0.006	0.004
None	R3 stream	0.050					0.032	0.018	0.013	0.009
50 %		0.040					0.028	0.016	0.012	0.008
75 %		0.036					0.026	0.015	0.011	0.008
90 %		0.033					0.025	0.014	0.011	0.008

Table 8.9-27: Global maximum PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to potatoes at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.778					0.255	0.135	0.092	0.070
50 %		0.389					0.127	0.068	0.046	0.035
75 %		0.194					0.064	0.034	0.023	0.018
90 %		0.078					0.025	0.014	0.009	0.007
None	D4 pond	0.031					0.028	0.020	0.016	0.013
50 %		0.016					0.014	0.010	0.008	0.007
75 %		0.008					0.007	0.005	0.004	0.003
90 %		0.003					0.003	0.002	0.002	0.001
None	D4 stream	0.607					0.256	0.136	0.093	0.070
50 %		0.304					0.128	0.068	0.046	0.035
75 %		0.152					0.064	0.034	0.023	0.018
90 %		0.061					0.026	0.014	0.009	0.007
None	D6 ditch 1st	0.769					0.252	0.134	0.091	0.069
50 %		0.385					0.126	0.067	0.046	0.035
75 %		0.192					0.063	0.033	0.023	0.017
90 %		0.077					0.025	0.013	0.009	0.007
None	D6 ditch 2nd	0.763					0.250	0.133	0.091	0.069
50 %		0.382					0.125	0.066	0.045	0.034
75 %		0.191					0.063	0.033	0.023	0.017
90 %		0.076					0.025	0.013	0.009	0.007
None	R1 pond	0.052					0.043	0.027	0.021	0.016
50 %		0.039					0.031	0.019	0.014	0.011
75 %		0.032					0.025	0.015	0.011	0.008
90 %		0.028					0.022	0.012	0.009	0.006

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.539					0.312*	0.180*	0.138*	0.094*
50 %		0.395*					0.312*	0.180*	0.138*	0.094*
75 %		0.395*					0.312*	0.180*	0.138*	0.094*
90 %		0.395*					0.312*	0.180*	0.138*	0.094*
None	R2 stream	0.712					0.300	0.159	0.109	0.083
50 %		0.356					0.150	0.080	0.054	0.041
75 %		0.178					0.093*	0.053*	0.041*	0.028*
90 %		0.119					0.093*	0.053*	0.041*	0.028*
None	R3 stream	0.759					0.320	0.170	0.116	0.088
50 %		0.380					0.160	0.085	0.058	0.044
75 %		0.190					0.092*	0.053*	0.041*	0.028*
90 %		0.117					0.092*	0.053*	0.041*	0.028*

* run-off/drainage induced

Table 8.9-28: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to potatoes at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.039					0.013	0.007	0.005	0.003
50 %		0.019					0.006	0.003	0.002	0.002
75 %		0.010					0.003	0.002	0.001	0.001
90 %		0.004					0.001	0.001	0.000	0.000
None	D4 pond	0.026					0.023	0.017	0.013	0.011
50 %		0.013					0.011	0.008	0.007	0.006
75 %		0.006					0.006	0.004	0.003	0.003
90 %		0.003					0.002	0.002	0.001	0.001
None	D4 stream	0.001					0.000	0.000	0.000	0.000
50 %		0.001					0.000	0.000	0.000	0.000
75 %		0.000					0.000	0.000	0.000	0.000
90 %		0.000					0.000	0.000	0.000	0.000
None	D6 ditch 1st	0.017					0.006	0.003	0.002	0.002
50 %		0.008					0.003	0.001	0.001	0.001
75 %		0.004					0.001	0.001	0.001	0.000
90 %		0.002					0.001	0.000	0.000	0.000
None	D6 ditch 2nd	0.011					0.004	0.002	0.001	0.001
50 %		0.006					0.002	0.001	0.001	0.000
75 %		0.003					0.001	0.000	0.000	0.000
90 %		0.001					0.000	0.000	0.000	0.000
None	R1 pond	0.044					0.036	0.023	0.018	0.014
50 %		0.033					0.026	0.016	0.012	0.009
75 %		0.027					0.021	0.012	0.009	0.007
90 %		0.024					0.018	0.010	0.008	0.005

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.021					0.015	0.008	0.006	0.004
50 %		0.018					0.014	0.008	0.006	0.004
75 %		0.017					0.013	0.007	0.006	0.004
90 %		0.016					0.013	0.007	0.006	0.004
None	R2 stream	0.007					0.004	0.002	0.002	0.001
50 %		0.005					0.004	0.002	0.002	0.001
75 %		0.005					0.004	0.002	0.002	0.001
90 %		0.005					0.004	0.002	0.002	0.001
None	R3 stream	0.013					0.005	0.003	0.002	0.002
50 %		0.007					0.004	0.002	0.002	0.001
75 %		0.006					0.004	0.002	0.002	0.001
90 %		0.006					0.004	0.002	0.002	0.001

Table 8.9-29: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to potatoes late at Step 4 (Tier 2. Foliar half-life 3.9 d)

PECSW [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.566					0.182	0.095	0.065	0.049
50 %		0.283					0.091	0.048	0.032	0.024
75 %		0.142					0.045	0.024	0.016	0.012
90 %		0.057					0.018	0.010	0.005	0.005
None	D4 pond	0.057					0.051	0.036	0.029	0.024
50 %		0.029					0.025	0.018	0.014	0.012
75 %		0.014					0.013	0.009	0.007	0.006
90 %		0.006					0.005	0.004	0.003	0.003
None	D4 stream	0.477					0.198	0.104	0.070	0.053
50 %		0.238					0.099	0.052	0.035	0.027
75 %		0.119					0.049	0.026	0.018	0.013
90 %		0.048					0.020	0.011	0.011	0.011
None	D6 ditch 1st	0.562					0.180	0.095	0.064	0.049
50 %		0.281					0.090	0.047	0.032	0.024
75 %		0.140					0.045	0.024	0.016	0.012
90 %		0.056					0.018	0.009	0.005	0.005
None	D6 ditch 2nd	0.568					0.439	0.439*	0.439*	0.439*
50 %		0.439*					0.439*	0.439*	0.439*	0.439*
75 %		0.439*					0.439*	0.439*	0.439*	0.439*
90 %		0.439*					0.439*	0.439*	0.439*	0.439*
None	R1 pond	0.051					0.045	0.032	0.025	0.021
50 %		0.025					0.022	0.016	0.013	0.011
75 %		0.013					0.011	0.008	0.006	0.005
90 %		0.005					0.004	0.003	0.002	0.002

PECSW [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.390					0.162	0.085	0.058	0.044
50 %		0.195					0.081	0.042	0.029	0.022
75 %		0.098					0.040	0.021	0.014	0.011
90 %		0.039					0.030	0.017	0.013	0.009
None	R2 stream	0.523					0.217	0.114	0.084	0.058
50 %		0.262					0.194*	0.110*	0.084*	0.057*
75 %		0.248*					0.194*	0.110*	0.084*	0.057*
90 %		0.248*					0.194*	0.110*	0.084*	0.057*
None	R3 stream	0.552					0.331*	0.191*	0.147*	0.100*
50 %		0.419*					0.331*	0.191*	0.147*	0.100*
75 %		0.419*					0.331*	0.191*	0.147*	0.100*
90 %		0.419*					0.331*	0.191*	0.147*	0.100*

* run-off/drainage induced ^not relevant for the central zone

Table 8.9-30: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to potatoes late at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.067					0.021	0.011	0.008	0.006
50 %		0.033					0.011	0.006	0.004	0.003
75 %		0.017					0.005	0.003	0.002	0.001
90 %		0.007					0.002	0.001	0.001	0.001
None	D4 pond	0.049					0.044	0.031	0.025	0.021
50 %		0.025					0.022	0.016	0.012	0.010
75 %		0.012					0.011	0.008	0.006	0.005
90 %		0.005					0.004	0.003	0.002	0.002
None	D4 stream	0.004					0.002	0.001	0.001	0.001
50 %		0.002					0.001	0.001	0.001	0.001
75 %		0.001					0.001	0.001	0.001	0.001
90 %		0.001					0.001	0.001	0.001	0.001
None	D6 ditch 1st	0.033					0.010	0.005	0.004	0.003
50 %		0.016					0.005	0.003	0.002	0.001
75 %		0.008					0.003	0.001	0.001	0.001
90 %		0.003					0.001	0.001	<0.001	<0.001
None	D6 ditch 2nd	0.103					0.033	0.017	0.013	0.011
50 %		0.051					0.016	0.011	0.009	0.008
75 %		0.026					0.011	0.008	0.007	0.007
90 %		0.012					0.007	0.007	0.006	0.006
None	R1 pond	0.043					0.038	0.027	0.021	0.018
50 %		0.021					0.019	0.014	0.011	0.009
75 %		0.011					0.009	0.007	0.005	0.004
90 %		0.004					0.004	0.003	0.002	0.002

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.006					0.002	0.001	0.001	0.001
50 %		0.003					0.001	0.001	<0.001	<0.001
75 %		0.001					0.001	0.001	<0.001	<0.001
90 %		0.001					0.001	0.001	<0.001	<0.001
None	R2 stream	0.016					0.011	0.006	0.005	0.003
50 %		0.014					0.010	0.005	0.004	0.003
75 %		0.012					0.009	0.005	0.004	0.003
90 %		0.012					0.009	0.005	0.004	0.003
None	R3 stream	0.075					0.048	0.027	0.020	0.014
50 %		0.060					0.042	0.024	0.018	0.013
75 %		0.053					0.039	0.022	0.017	0.012
90 %		0.048					0.037	0.022	0.016	0.011

^not relevant for the central zone

Table 8.9-31: Global maximum PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes late at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.778					0.255	0.135	0.092	0.070
50 %		0.389					0.128	0.068	0.046	0.035
75 %		0.195					0.064	0.034	0.023	0.018
90 %		0.078					0.026	0.014	0.009	0.007
None	D4 pond	0.031					0.028	0.020	0.016	0.013
50 %		0.016					0.014	0.010	0.008	0.007
75 %		0.008					0.007	0.005	0.004	0.003
90 %		0.003					0.003	0.002	0.002	0.001
None	D4 stream	0.585					0.246	0.131	0.089	0.068
50 %		0.292					0.123	0.065	0.045	0.034
75 %		0.146					0.062	0.033	0.022	0.017
90 %		0.058					0.025	0.013	0.009	0.007
None	D6 ditch 1st	0.773					0.253	0.134	0.092	0.070
50 %		0.387					0.127	0.067	0.046	0.035
75 %		0.193					0.063	0.034	0.023	0.017
90 %		0.077					0.025	0.013	0.009	0.007
None	D6 ditch 2nd	0.778					0.255	0.135	0.092	0.070
50 %		0.389					0.128	0.068	0.056*	0.056*
75 %		0.195					0.064	0.056*	0.056*	0.056*
90 %		0.078					0.056*	0.056*	0.056*	0.056*
None	R1 pond	0.031					0.028	0.020	0.016	0.013
50 %		0.016					0.014	0.010	0.008	0.007
75 %		0.008					0.007	0.005	0.004	0.003
90 %		0.003					0.003	0.002	0.002	0.001

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.535					0.225	0.119	0.082	0.062
50 %		0.267					0.113	0.060	0.041	0.031
75 %		0.134					0.056	0.030	0.020	0.016
90 %		0.053					0.023	0.012	0.008	0.006
None	R2 stream	0.712					0.300	0.159	0.109	0.083
50 %		0.356					0.150	0.080	0.054	0.041
75 %		0.178					0.119*	0.068*	0.052*	0.035*
90 %		0.152					0.119*	0.068*	0.052*	0.035*
None	R3 stream	0.761					0.320	0.170	0.116	0.088
50 %		0.381					0.251*	0.145*	0.111*	0.076*
75 %		0.317*					0.251*	0.145*	0.111*	0.076*
90 %		0.317*					0.251*	0.145*	0.111*	0.076*

* run-off/drainage induced ^not relevant for the central zone

Table 8.9-32: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to potatoes late at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D3 ditch	0.041					0.013	0.007	0.005	0.004
50 %		0.020					0.007	0.004	0.002	0.002
75 %		0.010					0.003	0.002	0.001	0.001
90 %		0.004					0.001	0.001	<0.001	<0.001
None	D4 pond	0.026					0.023	0.017	0.013	0.011
50 %		0.013					0.012	0.008	0.007	0.006
75 %		0.006					0.006	0.004	0.003	0.003
90 %		0.003					0.002	0.002	0.001	0.001
None	D4 stream	0.001					<0.001	<0.001	<0.001	<0.001
50 %		<0.001					<0.001	<0.001	<0.001	<0.001
75 %		<0.001					<0.001	<0.001	<0.001	<0.001
90 %		<0.001					<0.001	<0.001	<0.001	<0.001
None	D6 ditch 1st	0.022					0.007	0.004	0.003	0.002
50 %		0.011					0.004	0.002	0.001	0.001
75 %		0.006					0.002	0.001	0.001	0.001
90 %		0.002					0.001	<0.001	<0.001	<0.001
None	D6 ditch 2nd	0.043					0.014	0.007	0.005	0.004
50 %		0.021					0.007	0.004	0.003	0.002
75 %		0.011					0.003	0.002	0.001	0.001
90 %		0.004					0.001	0.001	0.001	0.001
None	R1 pond	0.026					0.023	0.017	0.013	0.011
50 %		0.013					0.011	0.008	0.007	0.006
75 %		0.006					0.006	0.004	0.003	0.003
90 %		0.003					0.002	0.002	0.001	0.001

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	R1 stream	0.004					0.002	0.001	0.001	<0.001
50 %		0.002					0.001	<0.001	<0.001	<0.001
75 %		0.001					<0.001	<0.001	<0.001	<0.001
90 %		<0.001					<0.001	<0.001	<0.001	<0.001
None	R2 stream	0.009					0.006	0.003	0.002	0.002
50 %		0.007					0.005	0.003	0.002	0.002
75 %		0.007					0.005	0.003	0.002	0.001
90 %		0.006					0.005	0.003	0.002	0.001
None	R3 stream	0.030					0.019	0.011	0.008	0.006
50 %		0.023					0.016	0.009	0.007	0.005
75 %		0.020					0.015	0.008	0.006	0.004
90 %		0.018					0.014	0.008	0.006	0.004

^not relevant for the central zone

Table 8.9-33: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.773						0.145	0.074	0.046
50 %		0.387						0.073	0.037	0.023
75 %		0.193						0.036	0.019	0.011
90 %		0.077						0.015	0.007	0.005
None	R1 pond	0.059						0.036	0.023	0.017
50 %		0.031						0.018	0.012	0.008
75 %		0.019						0.010	0.007	0.005
90 %		0.012						0.006	0.004	0.003
None	R1 stream	0.708*						0.299*	0.227*	0.153*
50 %		0.708*						0.299*	0.227*	0.153*
75 %		0.708*						0.299*	0.227*	0.153*
90 %		0.708*						0.299*	0.227*	0.153*
None	R2 stream	0.743						0.171	0.087	0.054
50 %		0.371						0.086	0.044	0.027
75 %		0.186						0.043	0.022	0.014
90 %		0.074						0.019	0.014	0.010
None	R3 stream	0.784						0.181	0.092	0.057
50 %		0.392						0.090	0.046	0.029
75 %		0.196						0.045	0.023	0.014
90 %		0.078						0.018	0.009	0.006
None	R4 stream	1.153*						0.504*	0.385*	0.263*
50 %		1.153*						0.504*	0.385*	0.263*
75 %		1.153*						0.504*	0.385*	0.263*
90 %		1.153*						0.504*	0.385*	0.263*

* run-off/drainage induced

Table 8.9-34: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.176						0.033	0.017	0.010
50 %		0.088						0.017	0.008	0.005
75 %		0.044						0.008	0.004	0.003
90 %		0.018						0.003	0.002	0.001
None	R1 pond	0.054						0.032	0.021	0.015
50 %		0.029						0.017	0.011	0.008
75 %		0.017						0.009	0.006	0.004
90 %		0.010						0.005	0.003	0.002
None	R1 stream	0.029						0.012	0.009	0.006
50 %		0.028						0.012	0.009	0.006
75 %		0.027						0.011	0.009	0.006
90 %		0.027						0.011	0.008	0.006
None	R2 stream	0.009						0.002	0.001	0.001
50 %		0.005						0.001	0.001	0.000
75 %		0.002						0.001	0.001	0.000
90 %		0.002						0.001	0.001	0.000
None	R3 stream	0.023						0.005	0.003	0.002
50 %		0.012						0.003	0.001	0.001
75 %		0.006						0.001	0.001	0.000
90 %		0.002						0.001	0.000	0.000
None	R4 stream	0.095						0.041	0.031	0.021
50 %		0.091						0.040	0.030	0.021
75 %		0.090						0.040	0.030	0.021
90 %		0.089						0.039	0.030	0.010

Table 8.9-35: Global maximum PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.829						0.174	0.093	0.059
50 %		0.415						0.087	0.046	0.030
75 %		0.207						0.044	0.023	0.015
90 %		0.083						0.017	0.009	0.006
None	R1 pond	0.029						0.018	0.012	0.009
50 %		0.014						0.009	0.006	0.004
75 %		0.007						0.005	0.003	0.002
90 %		0.003						0.002	0.001	0.001
None	R1 stream	0.611						0.155	0.083	0.053
50 %		0.306						0.078	0.041*	0.027*
75 %		0.153						0.054*	0.041*	0.027*
90 %		0.127						0.054*	0.041*	0.027*
None	R2 stream	0.812						0.206	0.110	0.070
50 %		0.406						0.103	0.055	0.035
75 %		0.203						0.052	0.028	0.018
90 %		0.081						0.021	0.011	0.007
None	R3 stream	0.865						0.220	0.117	0.075
50 %		0.432						0.110	0.059	0.037
75 %		0.216						0.055	0.029	0.019
90 %		0.086						0.022	0.012	0.007
None	R4 stream	0.605						0.167*	0.128*	0.087*
50 %		0.383*						0.167*	0.128*	0.087*
75 %		0.383*						0.167*	0.128*	0.087*
90 %		0.383*						0.167*	0.128*	0.087*

* run-off/drainage induced

Table 8.9-36: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.020						0.004	0.002	0.001
50 %		0.019						0.002	0.001	0.001
75 %		0.009						0.001	0.001	0.000
90 %		0.005						0.000	0.000	0.000
None	R1 pond	0.002						0.015	0.010	0.007
50 %		0.024						0.007	0.005	0.004
75 %		0.012						0.004	0.002	0.002
90 %		0.006						0.001	0.001	0.001
None	R1 stream	0.003						0.002	0.002	0.001
50 %		0.005						0.002	0.002	0.001
75 %		0.005						0.002	0.002	0.001
90 %		0.005						0.002	0.002	0.001
None	R2 stream	0.005						0.001	0.000	0.000
50 %		0.003						0.000	0.000	0.000
75 %		0.002						0.000	0.000	0.000
90 %		0.001						0.000	0.000	0.000
None	R3 stream	0.000						0.003	0.002	0.001
50 %		0.012						0.002	0.001	0.001
75 %		0.006						0.001	0.000	0.000
90 %		0.003						0.000	0.000	0.000
None	R4 stream	0.001						0.014	0.010	0.007
50 %		0.033						0.014	0.010	0.007
75 %		0.031						0.013	0.010	0.007
90 %		0.030						0.013	0.010	0.007

Table 8.9-37: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	3.156						0.677	0.365	0.234
50 %		1.577						0.338	0.182	0.117
75 %		0.788						0.169	0.091	0.058
90 %		0.315						0.067	0.036	0.027
None	R1 pond	0.192						0.122	0.082	0.061
50 %		0.096						0.061	0.041	0.030
75 %		0.048						0.030	0.020	0.015
90 %		0.019						0.012	0.008	0.006
None	R1 stream	1.592						0.413	0.223	0.143
50 %		0.796						0.207	0.111	0.071
75 %		0.398						0.103	0.056	0.036
90 %		0.159						0.041	0.028	0.019
None	R2 stream	2.134						0.554	0.298	0.192
50 %		1.067						0.277	0.149	0.096
75 %		0.533						0.138	0.075	0.048
90 %		0.213						0.055	0.030	0.019
None	R3 stream	2.244						0.582	0.314	0.201
50 %		1.122						0.309*	0.237*	0.162*
75 %		0.679						0.309*	0.237*	0.162*
90 %		0.679						0.309*	0.237*	0.162*
None	R4 stream	1.592						0.629*	0.481*	0.327*
50 %		1.405*						0.629*	0.481*	0.327*
75 %		1.405*						0.629*	0.481*	0.327*
90 %		1.405*						0.629*	0.481*	0.327*

* run-off/drainage induced

Table 8.9-38: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	1.856						0.397	0.214	0.137
50 %		0.927						0.198	0.107	0.069
75 %		0.463						0.099	0.053	0.034
90 %		0.185						0.040	0.021	0.014
None	R1 pond	0.165						0.105	0.070	0.052
50 %		0.082						0.052	0.035	0.026
75 %		0.041						0.026	0.018	0.013
90 %		0.016						0.010	0.007	0.005
None	R1 stream	0.032						0.008	0.004	0.003
50 %		0.016						0.004	0.002	0.001
75 %		0.008						0.002	0.001	0.001
90 %		0.003						0.001	0.001	0.001
None	R2 stream	0.022						0.006	0.003	0.002
50 %		0.011						0.003	0.002	0.001
75 %		0.005						0.001	0.001	0.000
90 %		0.002						0.001	0.001	0.000
None	R3 stream	0.140						0.052	0.036	0.025
50 %		0.110						0.044	0.032	0.022
75 %		0.096						0.041	0.030	0.021
90 %		0.087						0.038	0.029	0.020
None	R4 stream	0.111						0.041	0.028	0.019
50 %		0.087						0.034	0.025	0.017
75 %		0.075						0.031	0.023	0.016
90 %		0.068						0.030	0.022	0.015

Table 8.9-39: Global maximum PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	2.546						0.558	0.303	0.196
50 %		1.273						0.279	0.152	0.098
75 %		0.636						0.139	0.076	0.049
90 %		0.255						0.056	0.030	0.020
None	R1 pond	0.091						0.058	0.039	0.029
50 %		0.045						0.029	0.020	0.015
75 %		0.023						0.014	0.010	0.007
90 %		0.009						0.006	0.004	0.003
None	R1 stream	1.868						0.493	0.268	0.173
50 %		0.934						0.246	0.134	0.086
75 %		0.467						0.123	0.067	0.043
90 %		0.187						0.049	0.027	0.017
None	R2 stream	2.503						0.661	0.359	0.232
50 %		1.251						0.330	0.179	0.116
75 %		0.626						0.165	0.090	0.058
90 %		0.250						0.066	0.036	0.023
None	R3 stream	2.632						0.695	0.377	0.244
50 %		1.316						0.347	0.189	0.122
75 %		0.658						0.174	0.094	0.061
90 %		0.263						0.069	0.038	0.024
None	R4 stream	1.867						0.493	0.268	0.173
50 %		0.934						0.246	0.134	0.086
75 %		0.467						0.123	0.071*	0.048*
90 %		0.206						0.092	0.071*	0.048*

* run-off/drainage induced

Table 8.9-40: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.846						0.185	0.100	0.065
50 %		0.422						0.092	0.050	0.032
75 %		0.211						0.046	0.025	0.016
90 %		0.084						0.018	0.010	0.006
None	R1 pond	0.075						0.048	0.032	0.024
50 %		0.037						0.024	0.016	0.012
75 %		0.019						0.012	0.008	0.006
90 %		0.007						0.005	0.003	0.002
None	R1 stream	0.019						0.005	0.003	0.002
50 %		0.009						0.002	0.001	0.001
75 %		0.005						0.001	0.001	0.000
90 %		0.002						0.000	0.000	0.000
None	R2 stream	0.013						0.003	0.002	0.001
50 %		0.006						0.002	0.001	0.001
75 %		0.003						0.001	0.000	0.000
90 %		0.001						0.000	0.000	0.000
None	R3 stream	0.056						0.017	0.010	0.007
50 %		0.033						0.010	0.007	0.004
75 %		0.021						0.007	0.005	0.003
90 %		0.014						0.006	0.004	0.003
None	R4 stream	0.028						0.009	0.006	0.004
50 %		0.019						0.007	0.005	0.003
75 %		0.014						0.005	0.004	0.003
90 %		0.011						0.005	0.003	0.002

* run-off/drainage induced

Table 8.9-41: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 1**. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.687						0.129	0.066	0.041
50 %		0.344						0.065	0.033	0.020
75 %		0.172						0.032	0.016	0.010
90 %		0.069						0.013	0.007	0.004
None	R1 pond	0.053						0.032	0.021	0.015
50 %		0.028						0.016	0.011	0.008
75 %		0.018						0.009	0.006	0.004
90 %		0.012						0.006	0.004	0.003
None	R1 stream	0.702*						0.297*	0.225*	0.151*
50 %		0.702*						0.297*	0.225*	0.151*
75 %		0.702*						0.297*	0.225*	0.151*
90 %		0.702*						0.297*	0.225*	0.151*
None	R2 stream	0.660						0.152	0.078	0.048
50 %		0.330						0.076	0.039	0.024
75 %		0.165						0.038	0.019	0.012
90 %		0.066						0.020	0.016	0.011
None	R3 stream	0.697						0.161	0.082	0.051
50 %		0.348						0.080	0.041	0.025
75 %		0.174						0.040	0.021	0.013
90 %		0.070						0.016	0.008	0.005
None	R4 stream	1.251*						0.557*	0.427*	0.291*
50 %		1.251*						0.557*	0.427*	0.291*
75 %		1.251*						0.557*	0.427*	0.291*
90 %		1.251*						0.557*	0.427*	0.291*

* run-off/drainage induced

Table 8.9-42: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 1**, Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.157						0.029	0.015	0.009
50 %		0.078						0.015	0.007	0.005
75 %		0.039						0.007	0.004	0.002
90 %		0.016						0.003	0.001	0.001
None	R1 pond	0.049						0.028	0.019	0.013
50 %		0.026						0.015	0.010	0.007
75 %		0.016						0.008	0.006	0.004
90 %		0.010						0.005	0.003	0.002
None	R1 stream	0.029						0.012	0.009	0.006
50 %		0.028						0.012	0.009	0.006
75 %		0.027						0.011	0.009	0.006
90 %		0.027						0.011	0.009	0.006
None	R2 stream	0.008						0.002	0.001	0.001
50 %		0.004						0.001	0.001	0.001
75 %		0.002						0.001	0.001	0.001
90 %		0.002						0.001	0.001	0.001
None	R3 stream	0.021						0.005	0.002	0.002
50 %		0.010						0.002	0.001	0.001
75 %		0.005						0.001	0.001	0.000
90 %		0.002						0.000	0.000	0.000
None	R4 stream	0.103						0.045	0.034	0.023
50 %		0.100						0.044	0.033	0.023
75 %		0.098						0.044	0.033	0.023
90 %		0.097						0.043	0.033	0.023

Table 8.9-43: Global maximum PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 1**. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.737						0.155	0.083	0.053
50 %		0.369						0.077	0.041	0.026
75 %		0.184						0.039	0.021	0.013
90 %		0.074						0.015	0.008	0.005
None	R1 pond	0.025						0.016	0.011	0.008
50 %		0.013						0.008	0.005	0.004
75 %		0.006						0.004	0.003	0.002
90 %		0.003						0.002	0.001	0.001
None	R1 stream	0.543						0.138	0.074	0.047
50 %		0.272						0.069	0.039*	0.026*
75 %		0.136						0.052*	0.039*	0.026*
90 %		0.122						0.052*	0.039*	0.026*
None	R2 stream	0.722						0.184	0.098	0.063
50 %		0.361						0.092	0.049	0.031
75 %		0.180						0.046	0.025	0.016
90 %		0.072						0.018	0.010	0.006
None	R3 stream	0.769						0.195	0.104	0.067
50 %		0.384						0.098	0.052	0.033
75 %		0.192						0.049	0.026	0.017
90 %		0.077						0.020	0.010	0.007
None	R4 stream	0.538						0.205*	0.157*	0.107*
50 %		0.457*						0.205*	0.157*	0.107*
75 %		0.457*						0.205*	0.157*	0.107*
90 %		0.457*						0.205*	0.157*	0.107*

* run-off/drainage induced

Table 8.9-44: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 1**, Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.017						0.004	0.002	0.001
50 %		0.008						0.002	0.001	0.001
75 %		0.004						0.001	0.000	0.000
90 %		0.002						0.000	0.000	0.000
None	R1 pond	0.021						0.013	0.009	0.006
50 %		0.011						0.007	0.004	0.003
75 %		0.005						0.003	0.002	0.002
90 %		0.002						0.001	0.001	0.001
None	R1 stream	0.005						0.002	0.001	0.001
50 %		0.005						0.002	0.001	0.001
75 %		0.005						0.002	0.001	0.001
90 %		0.005						0.002	0.001	0.001
None	R2 stream	0.003						0.001	0.000	0.000
50 %		0.001						0.000	0.000	0.000
75 %		0.001						0.000	0.000	0.000
90 %		0.000						0.000	0.000	0.000
None	R3 stream	0.011						0.003	0.001	0.001
50 %		0.006						0.001	0.001	0.000
75 %		0.003						0.001	0.000	0.000
90 %		0.001						0.000	0.000	0.000
None	R4 stream	0.039						0.017	0.013	0.009
50 %		0.037						0.016	0.012	0.008
75 %		0.036						0.016	0.012	0.008
90 %		0.036						0.016	0.012	0.008

* run-off/drainage induced

Table 8.9-45: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 1**. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	2.805						0.601	0.324	0.208
50 %		1.401						0.301	0.162	0.104
75 %		0.700						0.150	0.081	0.052
90 %		0.280						0.060	0.045	0.045
None	R1 pond	0.170						0.108	0.073	0.054
50 %		0.085						0.054	0.036	0.027
75 %		0.043						0.027	0.018	0.013
90 %		0.017						0.011	0.007	0.005
None	R1 stream	1.415						0.367	0.198	0.127
50 %		0.707						0.184	0.099	0.064
75 %		0.354						0.092	0.056	0.038
90 %		0.163						0.073	0.056	0.038
None	R2 stream	1.896						0.492	0.265	0.170
50 %		0.948						0.246	0.133	0.085
75 %		0.474						0.123	0.066	0.043
90 %		0.190						0.049	0.027	0.017
None	R3 stream	1.994						0.518	0.342*	0.234*
50 %		0.997						0.446*	0.342*	0.234*
75 %		0.981*						0.446*	0.342*	0.234*
90 %		0.981*						0.446*	0.342*	0.234*
None	R4 stream	2.078*						0.929*	0.711*	0.484*
50 %		2.078*						0.929*	0.711*	0.484*
75 %		2.078*						0.929*	0.711*	0.484*
90 %		2.078*						0.929*	0.711*	0.484*

* run-off/drainage induced

Table 8.9-46: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 1**. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	1.649						0.353	0.190	0.122
50 %		0.823						0.176	0.095	0.061
75 %		0.411						0.088	0.047	0.030
90 %		0.164						0.035	0.019	0.012
None	R1 pond	0.147						0.093	0.062	0.046
50 %		0.073						0.046	0.031	0.023
75 %		0.037						0.023	0.016	0.012
90 %		0.015						0.009	0.006	0.005
None	R1 stream	0.028						0.007	0.004	0.003
50 %		0.014						0.004	0.002	0.001
75 %		0.007						0.002	0.002	0.001
90 %		0.005						0.002	0.002	0.001
None	R2 stream	0.019						0.005	0.003	0.002
50 %		0.010						0.003	0.001	0.001
75 %		0.005						0.001	0.001	0.001
90 %		0.002						0.001	0.001	0.001
None	R3 stream	0.170						0.067	0.049	0.033
50 %		0.144						0.061	0.045	0.031
75 %		0.131						0.057	0.043	0.029
90 %		0.124						0.055	0.042	0.029
None	R4 stream	0.136						0.053	0.038	0.026
50 %		0.115						0.047	0.035	0.024
75 %		0.105						0.045	0.033	0.023
90 %		0.098						0.043	0.033	0.022

Table 8.9-47: Global maximum PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 1**. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	2.263						0.496	0.269	0.174
50 %		1.132						0.248	0.135	0.087
75 %		0.566						0.124	0.067	0.043
90 %		0.226						0.050	0.027	0.017
None	R1 pond	0.081						0.052	0.035	0.026
50 %		0.040						0.026	0.017	0.013
75 %		0.020						0.013	0.009	0.006
90 %		0.008						0.005	0.003	0.003
None	R1 stream	1.660						0.438	0.238	0.154
50 %		0.830						0.219	0.119	0.077
75 %		0.415						0.110	0.059	0.038
90 %		0.166						0.044	0.024	0.015
None	R2 stream	2.225						0.587	0.319	0.206
50 %		1.112						0.294	0.160	0.103
75 %		0.556						0.147	0.080	0.051
90 %		0.223						0.059	0.032	0.021
None	R3 stream	2.340						0.618	0.335	0.217
50 %		1.170						0.309	0.168	0.108
75 %		0.585						0.154	0.084	0.054
90 %		0.234						0.096	0.074	0.050
None	R4 stream	1.660						0.438	0.238	0.154
50 %		0.830						0.232*	0.177*	0.121*
75 %		0.518*						0.232*	0.177*	0.121*
90 %		0.518*						0.232*	0.177*	0.121*

* run-off/drainage induced

Table 8.9-48: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 1**. Foliar half-life 10 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.751						0.164	0.089	0.057
50 %		0.375						0.082	0.044	0.029
75 %		0.187						0.041	0.022	0.014
90 %		0.075						0.016	0.009	0.006
None	R1 pond	0.067						0.043	0.029	0.021
50 %		0.033						0.021	0.014	0.011
75 %		0.017						0.011	0.007	0.005
90 %		0.007						0.004	0.003	0.002
None	R1 stream	0.017						0.004	0.002	0.002
50 %		0.008						0.002	0.001	0.001
75 %		0.004						0.001	0.001	0.000
90 %		0.002						0.000	0.000	0.000
None	R2 stream	0.011						0.003	0.002	0.001
50 %		0.006						0.001	0.001	0.001
75 %		0.003						0.001	0.000	0.000
90 %		0.001						0.000	0.000	0.000
None	R3 stream	0.066						0.022	0.014	0.010
50 %		0.045						0.017	0.011	0.008
75 %		0.035						0.014	0.010	0.007
90 %		0.029						0.012	0.009	0.006
None	R4 stream	0.040						0.015	0.010	0.007
50 %		0.032						0.013	0.009	0.006
75 %		0.028						0.012	0.009	0.006
90 %		0.025						0.011	0.008	0.006

Table 8.9-49: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 2**, Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.687						0.129	0.066	0.041
50 %		0.344						0.065	0.033	0.020
75 %		0.172						0.032	0.016	0.010
90 %		0.069						0.013	0.007	0.004
None	R1 pond	0.053						0.032	0.021	0.015
50 %		0.028						0.016	0.010	0.007
75 %		0.017						0.009	0.006	0.004
90 %		0.011						0.005	0.004	0.003
None	R1 stream	0.627*						0.265*	0.201*	0.135*
50 %		0.627*						0.265*	0.201*	0.135*
75 %		0.627*						0.265*	0.201*	0.135*
90 %		0.627*						0.265*	0.201*	0.135*
None	R2 stream	0.660						0.152	0.078	0.048
50 %		0.330						0.076	0.039	0.024
75 %		0.165						0.038	0.019	0.012
90 %		0.066						0.016	0.013	0.009
None	R3 stream	0.697						0.161	0.082	0.051
50 %		0.348						0.080	0.041	0.025
75 %		0.174						0.040	0.021	0.013
90 %		0.070						0.016	0.008	0.005
None	R4 stream	1.023*						0.447*	0.342*	0.233*
50 %		1.023*						0.447*	0.342*	0.233*
75 %		1.023*						0.447*	0.342*	0.233*
90 %		1.023*						0.447*	0.342*	0.233*

* run-off/drainage induced

Table 8.9-50: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 2**, Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.157						0.029	0.015	0.009
50 %		0.078						0.015	0.007	0.005
75 %		0.039						0.007	0.004	0.002
90 %		0.016						0.003	0.001	0.001
None	R1 pond	0.048						0.028	0.018	0.013
50 %		0.026						0.015	0.010	0.007
75 %		0.015						0.008	0.005	0.004
90 %		0.009						0.004	0.003	0.002
None	R1 stream	0.026						0.011	0.008	0.005
50 %		0.025						0.010	0.008	0.005
75 %		0.024						0.010	0.008	0.005
90 %		0.024						0.010	0.008	0.005
None	R2 stream	0.008						0.002	0.001	0.001
50 %		0.004						0.001	0.001	0.000
75 %		0.002						0.001	0.001	0.000
90 %		0.002						0.001	0.001	0.000
None	R3 stream	0.021						0.005	0.002	0.002
50 %		0.010						0.002	0.001	0.001
75 %		0.005						0.001	0.001	0.000
90 %		0.002						0.000	0.000	0.000
None	R4 stream	0.084						0.036	0.027	0.019
50 %		0.081						0.036	0.027	0.018
75 %		0.080						0.035	0.027	0.018
90 %		0.079						0.035	0.027	0.018

Table 8.9-51: Global maximum PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 2**. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.737						0.155	0.083	0.053
50 %		0.369						0.077	0.041	0.026
75 %		0.184						0.039	0.021	0.013
90 %		0.074						0.015	0.008	0.005
None	R1 pond	0.025						0.016	0.011	0.008
50 %		0.013						0.008	0.005	0.004
75 %		0.006						0.004	0.003	0.002
90 %		0.003						0.002	0.001	0.001
None	R1 stream	0.543						0.138	0.074	0.047
50 %		0.272						0.069	0.037	0.024
75 %		0.136						0.048	0.036	0.024
90 %		0.112						0.048	0.036	0.024
None	R2 stream	0.722						0.184	0.098	0.063
50 %		0.361						0.092	0.049	0.031
75 %		0.180						0.046	0.025	0.016
90 %		0.072						0.018	0.010	0.006
None	R3 stream	0.769						0.195	0.104	0.067
50 %		0.384						0.098	0.052	0.033
75 %		0.192						0.049	0.026	0.017
90 %		0.077						0.020	0.010	0.007
None	R4 stream	0.538						0.148*	0.114*	0.078*
50 %		0.340*						0.148*	0.114*	0.078*
75 %		0.340*						0.148*	0.114*	0.078*
90 %		0.340*						0.148*	0.114*	0.078*

* run-off/drainage induced

Table 8.9-52: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine early at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 2**, Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.018						0.004	0.002	0.001
50 %		0.017						0.002	0.001	0.001
75 %		0.008						0.001	0.000	0.000
90 %		0.004						0.000	0.000	0.000
None	R1 pond	0.002						0.013	0.009	0.006
50 %		0.021						0.007	0.004	0.003
75 %		0.011						0.003	0.002	0.002
90 %		0.005						0.001	0.001	0.001
None	R1 stream	0.002						0.002	0.001	0.001
50 %		0.004						0.002	0.001	0.001
75 %		0.004						0.002	0.001	0.001
90 %		0.004						0.002	0.001	0.001
None	R2 stream	0.004						0.001	0.000	0.000
50 %		0.003						0.000	0.000	0.000
75 %		0.001						0.000	0.000	0.000
90 %		0.001						0.000	0.000	0.000
None	R3 stream	0.000						0.003	0.001	0.001
50 %		0.011						0.001	0.001	0.000
75 %		0.006						0.001	0.000	0.000
90 %		0.003						0.000	0.000	0.000
None	R4 stream	0.001						0.012	0.009	0.006
50 %		0.029						0.012	0.009	0.006
75 %		0.028						0.012	0.009	0.006
90 %		0.027						0.012	0.009	0.006

* run-off/drainage induced

Table 8.9-53: Global maximum PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 2**. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	2.805						0.601	0.324	0.208
50 %		1.401						0.301	0.162	0.104
75 %		0.700						0.150	0.081	0.052
90 %		0.280						0.060	0.032	0.024
None	R1 pond	0.170						0.108	0.073	0.054
50 %		0.085						0.054	0.036	0.027
75 %		0.043						0.027	0.018	0.013
90 %		0.017						0.011	0.007	0.005
None	R1 stream	1.415						0.367	0.198	0.127
50 %		0.707						0.184	0.099	0.064
75 %		0.354						0.092	0.049	0.032
90 %		0.142						0.037	0.025	0.017
None	R2 stream	1.896						0.492	0.265	0.170
50 %		0.948						0.246	0.133	0.085
75 %		0.474						0.123	0.066	0.043
90 %		0.190						0.049	0.027	0.017
None	R3 stream	1.994						0.518	0.279	0.179
50 %		0.997						0.274*	0.210*	0.143*
75 %		0.602*						0.274*	0.210*	0.143*
90 %		0.602*						0.274*	0.210*	0.143*
None	R4 stream	1.415*						0.557*	0.426*	0.290*
50 %		1.415*						0.557*	0.426*	0.290*
75 %		1.415*						0.557*	0.426*	0.290*
90 %		1.415*						0.557*	0.426*	0.290*

* run-off/drainage induced

Table 8.9-54: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following multiple application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 2**, Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	1.649						0.353	0.190	0.122
50 %		0.823						0.176	0.095	0.061
75 %		0.411						0.088	0.047	0.030
90 %		0.164						0.035	0.019	0.012
None	R1 pond	0.147						0.093	0.062	0.046
50 %		0.073						0.046	0.031	0.023
75 %		0.037						0.023	0.016	0.012
90 %		0.015						0.009	0.006	0.005
None	R1 stream	0.028						0.007	0.004	0.003
50 %		0.014						0.004	0.002	0.001
75 %		0.007						0.002	0.001	0.001
90 %		0.003						0.001	0.001	0.001
None	R2 stream	0.019						0.005	0.003	0.002
50 %		0.010						0.003	0.001	0.001
75 %		0.005						0.001	0.001	0.000
90 %		0.002						0.001	0.000	0.000
None	R3 stream	0.124						0.046	0.032	0.022
50 %		0.098						0.039	0.029	0.019
75 %		0.085						0.036	0.027	0.018
90 %		0.077						0.034	0.026	0.018
None	R4 stream	0.099						0.036	0.025	0.017
50 %		0.077						0.031	0.022	0.015
75 %		0.067						0.028	0.021	0.014
90 %		0.061						0.026	0.020	0.013

Table 8.9-55: Global maximum PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (reduced dose 3 * 132 g/ha zoxamide, **Tier 2**. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	2.263						0.496	0.269	0.174
50 %		1.132						0.248	0.135	0.087
75 %		0.566						0.124	0.067	0.043
90 %		0.226						0.050	0.027	0.017
None	R1 pond	0.081						0.052	0.035	0.026
50 %		0.040						0.026	0.017	0.013
75 %		0.020						0.013	0.009	0.006
90 %		0.008						0.005	0.003	0.003
None	R1 stream	1.660						0.438	0.238	0.154
50 %		0.830						0.219	0.119	0.077
75 %		0.415						0.110	0.059	0.038
90 %		0.166						0.044	0.024	0.015
None	R2 stream	2.225						0.587	0.319	0.206
50 %		1.112						0.294	0.160	0.103
75 %		0.556						0.147	0.080	0.051
90 %		0.223						0.059	0.032	0.021
None	R3 stream	2.340						0.618	0.335	0.217
50 %		1.170						0.309	0.168	0.108
75 %		0.585						0.154	0.084	0.054
90 %		0.234						0.062	0.034	0.022
None	R4 stream	1.660						0.438	0.238	0.154
50 %		0.830						0.219	0.119	0.077
75 %		0.415						0.110	0.063*	0.043*
90 %		0.183						0.082	0.063*	0.043*

* run-off/drainage induced

Table 8.9-56: Maximum 21 d TWA-PEC_{sw} values for zoxamide, following single application(s) of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ to vine late at Step 4 (reduced dose 3 * 132 g/ha zoxamide, Tier 2. Foliar half-life 3.9 d)

PEC _{sw} [µg/L]	Scenario	STEP 4								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	15	20
None	D6 ditch	0.751						0.164	0.089	0.057
50 %		0.375						0.082	0.044	0.029
75 %		0.187						0.041	0.022	0.014
90 %		0.075						0.016	0.009	0.006
None	R1 pond	0.067						0.043	0.029	0.021
50 %		0.033						0.021	0.014	0.011
75 %		0.017						0.011	0.007	0.005
90 %		0.007						0.004	0.003	0.002
None	R1 stream	0.017						0.004	0.002	0.002
50 %		0.008						0.002	0.001	0.001
75 %		0.004						0.001	0.001	0.000
90 %		0.002						0.000	0.000	0.000
None	R2 stream	0.011						0.003	0.002	0.001
50 %		0.006						0.001	0.001	0.001
75 %		0.003						0.001	0.000	0.000
90 %		0.001						0.000	0.000	0.000
None	R3 stream	0.050						0.015	0.009	0.006
50 %		0.029						0.009	0.006	0.004
75 %		0.019						0.007	0.004	0.003
90 %		0.013						0.005	0.004	0.002
None	R4 stream	0.025						0.008	0.005	0.003
50 %		0.017						0.006	0.004	0.003
75 %		0.012						0.005	0.003	0.002
90 %		0.010						0.004	0.003	0.002

* run-off/drainage induced

Metabolite(s) of zoxamide

In the following tables, the surface water and sediment PEC values for the relevant metabolites of zoxamide are depicted. The PECs were calculated using FOCUS Step 1/2 version 3.2.

Table 8.9-57: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for RH-127450 following single/multiple application(s) to vines, early

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d-PEC _{sw, twa} (µg/L)	21 d-PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
Step 1	---	41.904		run-off	41.9044		240.1095	
Step 2								
Northern Europe	March-May	2.375	1.276	run-off	2.185	1.195	13.303	7.276
Southern Europe	March-May	3.903	2.246	run-off	3.668	2.136	22.342	13.015

* single application

Table 8.9-58: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for RH-127450 following single/multiple application(s) to vines, late

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d-PEC _{sw, twa} (µg/L)	21 d-PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
Step 1	---	44.696		run-off	41.594		240.110	
Step 2								
Northern Europe	June - September	3.311	1.554	run-off	2.892	1.381	17.580	8.400
Southern Europe	June - September	3.820	1.878	run-off	3.386	1.695	20.593	10.313

* single application

Table 8.9-59: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for RH-127450 following single/multiple application(s) to potato early

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d-PEC _{sw, twa} (µg/L)	21 d-PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)	Max PEC _{sed} (µg/kg)*
Step 1	---	41.936		run-off	40.070		240.110	
Step 2								
Northern Europe	March-May	2.838	1.687	run-off	2.659	1.687	16.195	1.687
Southern Europe	March-May	5.004	3.062	run-off	4.759	2.926	29.000	17.832

* single application

Table 8.9-60: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-127450 following single/multiple application(s) to potato late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw,twa (µg/L)	21 d-PECsw,twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	41.936		run-off	40.070		240.110	
Step 2								
Northern Europe	June - September	1.4367	0.7971	run-off	1.2998	0.7297	7.9096	4.4414
Southern Europe	June - September	1.8189	1.0398	run-off	1.6705	0.9650	10.1692	5.8760

* single application

The following PECsw and PECsed values for RH24549 were only calculated considering worst-case DT₅₀ values.

Table 8.9-61: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-24549 following single/multiple application(s) to vines, early

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw,twa (µg/L)	21 d-PECsw,twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	31.428		run-off	31.1125		28.3478	
Step 2								
Northern Europe	June - September	1.521	0.862	run-off	1.507	0.855	1.373	0.779
Southern Europe	June - September	2.937	1.687	run-off	2.912	1.674	2.654	1.526

* single application

Table 8.9-62: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-24549 following single/multiple application(s) to vines, late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw,twa (µg/L)	21 d-PECsw,twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	31.669		run-off	31.402		28.348	
Step 2								
Northern Europe	June - September	1.230	0.662	run-off	1.211	0.653	1.104	0.595
Southern Europe	June - September	1.702	0.937	run-off	1.680	0.926	1.531	0.844

* single application

Table 8.9-63: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-24549 following single/multiple application(s) to potato early

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw,twa (µg/L)	21 d-PECsw,twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	31.431		run-off	31.190		28.348	

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 2								
Northern Europe	March-May	2.090	1.207	run-off	2.072	1.197	1.888	1.091
Southern Europe	March-May	4.095	2.375	run-off	4.063	2.357	3.703	2.148

* single application

Table 8.9-64: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-24549 following single/multiple application(s) to potato late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	31.431		run-off	31.190		28.348	
Step 2								
Northern Europe	June - September	0.7919	0.4508	run-off	0.7832	0.4462	0.7138	0.4067
Southern Europe	June - September	1.1458	0.6570	run-off	1.1346	0.6509	1.0341	0.5932

* single application

Table 8.9-65: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-163353 following single/multiple application(s) to vines, early

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	48.638		run-off	48.220		32.520	
Step 2								
Northern Europe	March-May	3.054	1.548	run-off	3.013	1.529	2.062	1.047
Southern Europe	March-May	5.389	2.840	run-off	5.331	2.812	3.649	1.925

* single application

Table 8.9-66: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-163353 following single/multiple application(s) to vines, late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	50.246		run-off	49.687		32.520	
Step 2								
Northern Europe	June - September	3.505	1.621	run-off	3.428	1.589	2.345	1.087
Southern Europe	June - September	4.284	2.052	run-off	4.200	2.016	2.874	1.380

* single application

Table 8.9-67: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-163353 following single/multiple application(s) to potato early

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	48.656		run-off	48.237		32.520	
Step 2								
Northern Europe	March-May	3.8798	2.092	run-off	3.836	2.069	2.626	1.416
Southern Europe	March-May	7.1880	3.922	run-off	7.121	3.887	4.874	2.660

* single applications.

Table 8.9-68: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-163353 following single/multiple application(s) to potato late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	48.656		run-off	48.237		32.520	
Step 2								
Northern Europe	June - September	1.7393	0.9071	run-off	1.7113	0.8935	1.1711	0.6115
Southern Europe	June - September	2.3231	1.2301	run-off	2.2909	1.2142	1.5678	0.8310

* single applications.

Table 8.9-69: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-141455 following single/multiple application(s) to vines, early

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	10.9036		run-off	10.8244		0.3037	
Step 2								
Northern Europe	March-May	0.568	0.311	run-off	0.564	0.309	0.016	0.009
Southern Europe	March-May	1.082	0.603	run-off	1.074	0.599	0.030	0.017

* single application

Table 8.9-70: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-141455 following single/multiple application(s) to vines, late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	11.020		run-off	10.940		0.304	
Step 2								
Northern Europe	June - September	0.491	0.2526	run-off	0.487	0.251	0.014	0.007

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Southern Europe	June - September	0.662	0.3499	run-off	0.657	0.347	0.019	0.010

* single application

Table 8.9-71: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-141455 following single/multiple application(s) to potato early

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	10.905		run-off	10.826		0.304	
Step 2								
Northern Europe	March-May	0.771	0.434	run-off	0.765	0.430	0.022	0.012
Southern Europe	March-May	1.498	0.847	run-off	1.487	0.841	0.042	0.024

* single application

Table 8.9-72: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-141455 following single/multiple application(s) to potato late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	10.905		run-off	10.826		0.304	
Step 2								
Northern Europe	June - September	0.3003	0.1659	run-off	0.2980	0.1647	0.0084	0.0046
Southern Europe	June - September	0.4286	0.2389	run-off	0.4254	0.2371	0.0120	0.0067

* single application

Table 8.9-73: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-141455 following single/multiple application(s) to vines, early assessment based on EU endpoints (EFSA, 2017)

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	10.9036		run-off	10.8244		0.3037	
Step 2								
Northern Europe	March-May	0.8580	0.3731	run-off	0.8517	0.3704	0.0240	0.0104
Southern Europe	March-May	1.6612	0.7268	run-off	1.6491	0.7215	0.0465	0.0203

* single application

Table 8.9-74: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-141455 following single/multiple application(s) to vines, late assessment based on EU endpoints (EFSA, 2017)

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw,twa (µg/L)	21 d-PECsw,twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	11.020		run-off	10.940		0.304	
Step 2								
Northern Europe	June - September	0.6841	0.2937	run-off	0.6790	0.2915	0.0191	0.0082
Southern Europe	June - September	0.9518	0.4116	run-off	0.9447	0.4086	0.0266	0.0115

* single application

Table 8.9-75: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-141455 following single/multiple application(s) to potato early assessment based on EU endpoints (EFSA, 2017)

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw,twa (µg/L)	21 d-PECsw,twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	10.905		run-off	10.826		0.304	
Step 2								
Northern Europe	March-May	1.1814	0.5209	run-off	1.1728	0.5171	0.0331	0.0146
Southern Europe	March-May	2.3192	1.0220	run-off	2.3023	1.0145	0.0649	0.0286

* single application

Table 8.9-76: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-141455 following single/multiple application(s) to potato late assessment based on EU endpoints (EFSA, 2017)

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw,twa (µg/L)	21 d-PECsw,twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	10.905		run-off	10.826		0.304	
Step 2								
Northern Europe	June - September	0.4452	0.1967	run-off	0.4419	0.1953	0.0125	0.0055
Southern Europe	June - September	0.6460	0.2852	run-off	0.6412	0.2831	0.0181	0.0080

* single application

Table 8.9-77: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-139432 following single/multiple application(s) to vines, early

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw,twa (µg/L)	21 d-PECsw,twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	23.882		run-off	23.702		2.336	

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 2								
Northern Europe	March-May	1.729	0.804	run-off	1.714	0.798	0.1726	0.080
Southern Europe	March-May	2.975	1.437	run-off	2.952	1.426	0.2971	0.144

* single application

Table 8.9-78: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-139432 following single/multiple application(s) to vines, late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	24.908		run-off	24.708		2.336	
Step 2								
Northern Europe	June - September	2.1380	0.932	run-off	2.117	0.923	0.213	0.093
Southern Europe	June - September	2.554	1.142	run-off	2.529	1.132	0.255	0.114

* single application

Table 8.9-79: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-139432 following single/multiple application(s) to potato early

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	23.893		run-off	23.714		2.336	
Step 2								
Northern Europe	March-May	2.149	1.072	run-off	2.132	1.063	0.215	0.107
Southern Europe	March-May	3.915	1.968	run-off	3.885	1.953	0.391	0.197

* single application

Table 8.9-80: FOCUS Step 1, 2 and 3 PECsw and PECsed for RH-139432 following single/multiple application(s) to potato late

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Max PECsw (µg/L)*	Dominant entry route	21 d-PECsw, twa (µg/L)	21 d-PECsw, twa (µg/L)*	Max PECsed (µg/kg)	Max PECsed (µg/kg)*
Step 1	---	23.893		run-off	23.714		2.336	
Step 2								
Northern Europe	June - September	1.0067	0.4916	run-off	0.9978	0.4873	0.1004	0.0490
Southern Europe	June - September	1.3183	0.6498	run-off	1.3071	0.6443	0.1316	0.0649

* single application

8.9.2.2 Cymoxanil and its metabolites

The risk assessment provided for cymoxanil contains the consolidated version of the previous product evaluation, since that part does not require any update. The risk assessment is therefore based on the worst-case application pattern, related to the previous product GAP.

The PEC of cymoxanil and its metabolites in surface water (PEC_{sw} and PEC_{sed}) has been assessed with the FOCUS SW and the DT_{50} water/sediment values above reported.

6 applications with 0.45 kg/ha of Cymoxanil 33% + Zoxamide 33% WG (corresponding to 148.5 g Cymoxanil/ha) were considered on potato and 5 both on grape and tomato.

For grape following FOCUS indications and according to crop BBCH, a crop interception value corresponding to a minimum crop cover was selected for Step 1-2 calculations, combined both with grape early and late applications in Central and Southern Europe. Being late applications performed in October-February the worst case, the results related to these simulations were here reported.

Table 8.9-81: Input parameters related to active substance cymoxanil and metabolite(s) for PEC_{sw/sed} calculations STEP 1/2

Property	Cymoxanil	IN-U3204	IN-W3595	IN-JX915	IN –KQ960	IN-T4226	IN-R3273	IN-KP533	M5
Molar mass [g/mol]	198.2	198.2	128.1	198.2	216.9	142.1	171.2	160.1	198.2
Solubility in water (at 20°C) [mg/L]	783	783	783	783	783	783	783	783	783
Vapour pressure (at 20°C) [Pa]	1.5 x 10 ⁻⁴	-	-	-	-	-	-	-	-
K _{foc} (mL/g)	43.6	29.7	9.2	16.3	21.6 ⁺⁺	17.7	41.9	12.9	9.2
DT _{50,soil} (d)	1.7*	0.38**	2.71	1.08	3.49 ⁺⁺	1000	1000	1000	1000
DT _{50,water} (d)	0.3	0.4	3.0	1.7	47.4	4.6	6.3	2.6	1.4
DT _{50,sed} (d)	0.3	0.4	3.0	1.7	47.4	4.6	6.3	2.6	1.4
DT _{50,whole system} (d)	0.3	0.4	3.0	1.7	47.4	4.6	6.3	2.6	1.4
Maximum occurrence (%)	-	Soil: 24.7 Water/ sediment: 24.7	Soil: 10.1 Water/ sediment: 27.5	Soil:10.9 Water/ sediment: 8.5	Soil: 6.3 Water/ sediment: 14.3	Soil: 1.7 Water/ sediment: 12.0	Soil: 2.4 Water/ sediment: 5	Soil: 2.7 Water/ sediment: 26	Soil: - Water/ sediment: 22.9

* This value is different than the EFSA agreed value of 1.2d, but is conservative and has been used. This will not influence metabolite PEC_{sw} values at step 1 & 2

⁺⁺ In some cases, CRD step 2 PEC calculations slightly differed from the applicant PECs; however, in these cases the applicant's PECs were higher. For this reason, CRD considers the use of the above applicant PECs appropriate

**CRD modelling uses 0.4, from EFSA Scientific Report (2008) 167, 1-116

Results of Step 2 simulations, used also for aquatic risk assessment, are summarized in Tables below. CRD has validated the results and agrees with the figures stated (evaluator PECSW were very similar, but slightly lower than applicant values).

Table 8.9-82: PEC_{sw} for Cymoxanil Step 2 – Potato

Method of calculation		FOCUS Step 2			
Application rate		6 x 0.45 kg product/ha (corresp. to 148.5 g/ha Cymoxanil)			
Application time		March-May			
Main routes of entry		Spray drift, Runoff, Drainage			
PEC _(sw)		Northern EU		Southern EU	
		Multiple applications Actual (µg/L)	Multiple applications Time weighted average (µg/L)	Multiple applications Actual (µg/L)	Multiple applications Time weighted average (µg/L)
Initial		1.053	-	2.106	-
Short term	24h	0.105	0.579	0.209	1.157
	2d	0.010	0.318	0.021	0.636
	4d	< 0.001	0.161	< 0.001	0.321
Long term	7d	< 0.001	0.092	< 0.001	0.184
	14d	< 0.001	0.046	< 0.001	0.092
	21d	< 0.001	0.031	< 0.001	0.061
	28d	< 0.001	0.023	< 0.001	0.046
	42d	< 0.001	0.015	< 0.001	0.031
	50d	< 0.001	0.013	< 0.001	0.026
	100d	< 0.001	0.006	< 0.001	0.013

Table 8.9-83: PEC_{sed} for Cymoxanil Step 2 – Potato

Method of calculation		FOCUS Step 2			
Application rate		6 x 0.45 kg product/ha (corresp. to 148.5 g/ha Cymoxanil)			
Application time		March-May			
Main routes of entry		Spray drift, Runoff, Drainage			
PEC _(sed)		Northern EU		Southern EU	
		Multiple applications Actual (µg/kg)	Multiple applications Time weighted average (µg/kg)	Multiple applications Actual (µg/kg)	Multiple applications Time weighted average (µg/kg)
Initial		0.459	-	0.918	-
Short term	24h	0.046	0.252	0.091	0.505
	2d	0.005	0.139	0.009	0.277
	4d	< 0.001	0.070	< 0.001	0.140
Long term	7d	< 0.001	0.040	< 0.001	0.080
	14d	< 0.001	0.020	< 0.001	0.040
	21d	< 0.001	0.013	< 0.001	0.027
	28d	< 0.001	0.010	< 0.001	0.020
	42d	< 0.001	0.007	< 0.001	0.013
	50d	< 0.001	0.006	< 0.001	0.011
	100d	< 0.001	0.003	< 0.001	0.006

Table 8.9-84: PEC_{sw} for Cymoxanil Step 2 – Grape, late applications

Method of calculation		FOCUS Step 2			
Application rate		5 x 0.45 kg product/ha (corresp. to 148.5 g/ha Cymoxanil)			
Application time		October- February			
Main routes of entry		Spray drift, Runoff, Drainage			

PEC _(sw)		Northern EU		Southern EU	
		Multiple applications Actual (µg/L)	Multiple applications Time weighted average (µg/L)	Multiple applications Actual (µg/L)	Multiple applications Time weighted average (µg/L)
Initial		3.285	-	3.285	-
Short term	24h	0.314	1.799	0.314	1.799
	2d	0.031	0.986	0.031	0.986
	4d	2.915	0.862	2.332	0.789
Long term	7d	0.003	0.747	0.003	0.654
	14d	< 0.001	0.373	< 0.001	0.327
	21d	< 0.001	0.249	< 0.001	0.218
	28d	< 0.001	0.187	< 0.001	0.164
	42d	< 0.001	0.125	< 0.001	0.109
	50d	< 0.001	0.105	< 0.001	0.092
	100d	< 0.001	0.052	< 0.001	0.046

Table 8.9-85: PEC_{sed} for Cymoxanil Step 2 – Grape, late applications

Method of calculation		FOCUS Step 2			
Application rate		5 x 0.45 kg product/ha (corresp. to 148.5 g/ha Cymoxanil)			
Application time		October- February			
Main routes of entry		Spray drift, Runoff, Drainage			

PEC _(sed)		Northern EU		Southern EU	
		Multiple applications Actual (µg/kg)	Multiple applications Time weighted average (µg/kg)	Multiple applications Actual (µg/kg)	Multiple applications Time weighted average (µg/kg)
Initial		1.271	-	1.017	-
Short term	24h	0.126	0.699	0.101	0.559
	2d	0.013	0.384	0.010	0.307
	4d	< 0.001	0.194	< 0.001	0.155
Long term	7d	< 0.001	0.111	< 0.001	0.089
	14d	< 0.001	0.055	< 0.001	0.044
	21d	< 0.001	0.037	< 0.001	0.030
	28d	< 0.001	0.028	< 0.001	0.022
	42d	< 0.001	0.019	< 0.001	0.015
	50d	< 0.001	0.016	< 0.001	0.012
	100d	< 0.001	0.008	< 0.001	0.006

Maximum concentrations of cymoxanil on potato were calculated to be 2.106 µg/L for applications in Southern Europe. Maximum concentrations of cymoxanil on grape were found to be 3.285 µg/L for late applications both in Central and Southern Europe. On tomato cymoxanil maximum concentration was calculated to be 2.915 µg/L for early treatments (March-May) in Southern Europe.

Maximum concentrations of cymoxanil on grape were calculated to be 3.285 µg/L for late applications both in Central and Southern Europe. On tomato Cymoxanil maximum concentration was calculated to be 2.915 µg/L for early treatments (March-May) in Southern Europe.

The PEC_{SW} generated at Step-2 resulted in acceptable TER values based on the most sensitive aquatic organism. Hence further refinements to the exposure assessment were not necessary.

The PEC of cymoxanil metabolites in surface water (PEC_{SW} and PEC_{SED}) has been assessed with the FOCUS SW and the DT₅₀ water/sediment values established in the EU review and the new endpoints for metabolite IN-KQ960.

Table 8.9-86: Maximum predicted actual concentrations of in surface water (PEC_{SWactual}) and sediment (PEC_{SED actual}) for cymoxanil metabolites after applications of Cymoxanil 33% + Zoxamide 33% WG on potato (FOCUS Step 2)

Crop (FOCUS crop scenario)	No. appl.	Compound	Appl. rate A.I. [g a.s./ha]	Region and season of appl.	Drift [%]	Runoff + drainage [%]	Maximum PEC _{SW actual} [µg/L]	Maximum PEC _{SED actual} [µg/kg d.s.]
Potato	6	IN-U3204	148.5	N EU	1.631	2.00	0.199*	0.006
				S EU	1.631	4.00	0.199*	0.006
		IN-W3595		N EU	1.631	2.00	0.236	0.019
				S EU	1.631	4.00	0.394*	0.034
		IN-KQ960		N EU	1.631	2.00	0.714	0.036
				S EU	1.631	4.00	0.887*	0.045
		IN-T4226		N EU	1.631	2.00	0.414	0.070
				S EU	1.631	4.00	0.764*	0.131
		IN-JX915		N EU	1.631	2.00	0.487*	0.034
				S EU	1.631	4.00	0.487*	0.034
		IN-R3273		N EU	1.631	2.00	0.925	0.345
				S EU	1.631	4.00	1.502*	0.581
		IN-KP533		N EU	1.631	2.00	0.691	0.087
				S EU	1.631	4.00	1.321*	0.168
		M5		N EU	1.631	2.00	0.202*	0.008
				S EU	1.631	4.00	0.202*	0.008

* in **bold** worst-case values

Table 8.9-87: Actual and TWA of worst PEC_{SW} and PEC_{SED} for IN-U3204, IN-W3595 and IN-KQ960 (Step 2) on potato.

Method of calculation	FOCUS Step 2
Application rate	6 x 0.45 kg product/ha
Scenario	worst case scenario for each metabolite (Southern Europe)

PEC _(sw)		IN-U3204				IN-W3595				IN-KQ960			
Worst case		Potato, Southern EU*				Potato, Southern EU*				Potato, Southern EU*			
		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.199	-	0.006	-	0.394	-	0.034	-	0.887	-	0.045	-
Short term	24h	0.034	0.117	0.001	0.004	0.313	0.354	0.029	0.031	0.873	0.880	0.044	0.045
	2d	0.006	0.069	< 0.001	0.002	0.248	0.317	0.023	0.029	0.861	0.874	0.044	0.044
	4d	0.002	0.036	< 0.001	0.001	0.156	0.258	0.014	0.024	0.836	0.861	0.042	0.044
Long term	7d	< 0.001	0.021	< 0.001	0.001	0.078	0.196	0.007	0.018	0.800	0.842	0.010	0.043
	14d	< 0.001	0.010	< 0.001	< 0.001	0.016	0.118	0.001	0.011	0.722	0.801	0.037	0.041
	21d	< 0.001	0.007	< 0.001	< 0.001	0.003	0.081	< 0.001	0.007	0.652	0.763	0.033	0.039
	28d	< 0.001	0.005	< 0.001	< 0.001	0.001	0.061	< 0.001	0.006	0.588	0.727	0.030	0.037
	42d	< 0.001	0.003	< 0.001	< 0.001	< 0.001	0.041	< 0.001	0.004	0.479	0.662	0.024	0.034
	50d	< 0.001	0.003	< 0.001	< 0.001	< 0.001	0.034	< 0.001	0.003	0.427	0.629	0.022	0.032
	100d	< 0.001	0.001	< 0.001	< 0.001	< 0.001	0.017	< 0.001	0.002	0.205	0.466	0.010	0.024

* worst case scenario. All the other scenarios were simulated and will be provided under request.

Table 8.9-88: Actual and TWA of worst PEC_{SW} and PEC_{SED} for IN-T4226, IN-JX915 and IN-R3273 (Step 2) on potato.

Method of calculation	FOCUS Step 2
Application rate	6 x 0.45 kg product/ha
Scenario	worst case scenario for each metabolite (Southern Europe)

PEC _(sw)		IN-T4226				IN-KX915				IN-R3273			
Worst case		Potato, Southern EU*				Potato, Southern EU*				Potato, Southern EU*			
		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.764	-	0.131	-	0.487	-	0.034	-	1.502	-	0.581	-
Short term	24h	0.657	0.710	0.116	0.124	0.320	0.404	0.023	0.029	1.340	1.421	0.561	0.571
	2d	0.565	0.661	0.100	0.116	0.213	0.335	0.015	0.024	1.200	1.346	0.503	0.552
	4d	0.418	0.575	0.074	0.101	0.179	0.252	0.019	0.022	0.963	1.212	0.404	0.502
Long term	7d	0.266	0.473	0.047	0.083	0.052	0.189	0.006	0.018	0.692	1.045	0.290	0.434
	14d	0.093	0.319	0.016	0.056	0.003	0.103	< 0.001	0.010	0.321	0.764	0.134	0.318
	21d	0.032	0.232	0.006	0.041	< 0.001	0.069	< 0.001	0.007	0.148	0.584	0.062	0.244
	28d	0.011	0.179	0.002	0.032	< 0.001	0.052	< 0.001	0.005	0.069	0.464	0.029	0.194
	42d	0.001	0.121	< 0.001	0.021	< 0.001	0.035	< 0.001	0.003	0.015	0.321	0.006	0.134
	50d	< 0.001	0.102	< 0.001	0.018	< 0.001	0.029	< 0.001	0.003	0.006	0.271	0.003	0.113
	100d	< 0.001	0.051	< 0.001	0.009	< 0.001	0.015	< 0.001	0.001	< 0.001	0.136	< 0.001	0.057

* worst case scenario. All the other scenarios were simulated and will be provided under request

Table 8.9-89: Actual and TWA of worst PEC_{SW} and PEC_{SED} for IN-KP533 and M5 (Step 2) on potato

Method of calculation	FOCUS Step 2
Application rate	6 x 0.45 kg product/ha
Scenario	worst case scenario for each metabolite (Southern Europe)

PEC _(sw)		IN-KP533				M5			
Worst case		Potato, Southern EU*				Potato, Southern EU*			
		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		1.321	-	0.168	-	0.202	-	0.008	-
Short term	24h	1.012	1.166	0.131	0.149	0.122	0.162	0.005	0.006
	2d	0.775	1.030	0.100	0.132	0.074	0.130	0.003	0.005
	4d	0.455	0.817	0.059	0.105	0.028	0.089	0.002	0.003
Long term	7d	0.204	0.602	0.026	0.077	0.006	0.057	< 0.001	0.002
	14d	0.032	0.347	0.004	0.045	< 0.001	0.030	< 0.001	0.001
	21d	0.005	0.236	0.001	0.030	< 0.001	0.020	< 0.001	0.001
	28d	0.001	0.178	< 0.001	0.023	< 0.001	0.015	< 0.001	0.001
	42d	< 0.001	0.119	< 0.001	0.015	< 0.001	0.010	< 0.001	< 0.001
	50d	< 0.001	0.100	< 0.001	0.013	< 0.001	0.008	< 0.001	< 0.001
	100d	< 0.001	0.050	< 0.001	0.006	< 0.001	0.004	< 0.001	< 0.001

* worst case scenario. All the other scenarios were simulated and will be provided under request

Table 8.9-90: Maximum predicted actual concentrations of in surface water (PEC_{SWactual}) and sediment (PEC_{SED actual}) for cymoxanil metabolites after applications of Cymoxanil 33% + Zoxamide 33% WG on vine (early and late applications) (FOCUS Step 2)

Crop (FOCUS crop scenario)	No. appl.	Compound	Appl. rate A.I. [g a.s./ha]	Region and season of appl.	Drift [%]	Runoff + drainage [%]	Maximum PEC _{SW actual} [µg/L]	Maximum PEC _{SED actual} [µg/kg d.s.]
Vine, early applications	5	IN-U3204	148.5	N EU	2.3980	5.00	0.293	0.009
				S EU	2.3980	4.00	0.293	0.009
		IN-W3595		N EU	2.3980	5.00	0.509	0.044
				S EU	2.3980	4.00	0.427	0.036
		IN-KQ960		N EU	2.3980	5.00	1.099	0.056
				S EU	2.3980	4.00	1.009	0.051
		IN-T4226		N EU	2.3980	5.00	0.951	0.164
				S EU	2.3980	4.00	0.776	0.133
		IN-JX915		N EU	2.3980	5.00	0.662	0.047
				S EU	2.3980	4.00	0.662	0.047
		IN-R3273		N EU	2.3980	5.00	1.805	0.718
				S EU	2.3980	4.00	1.563	0.597
		IN-KP533		N EU	2.3980	5.00	1.651	0.210
				S EU	2.3980	4.00	1.337	0.169
		M5		N EU	2.3980	5.00	0.281	0.010
				S EU	2.3980	4.00	0.281	0.010
Vine, late applications	5	IN-U3204	148.5	N EU	6.636	5.00	0.811*	0.026
				S EU	6.636	4.00	0.811	0.026
		IN-W3595		N EU	6.636	5.00	0.690*	0.055
				S EU	6.636	4.00	0.690	0.047
		IN-KQ960		N EU	6.636	5.00	2.249*	0.114
				S EU	6.636	4.00	2.159	0.109
		IN-T4226		N EU	6.636	5.00	1.088*	0.180
				S EU	6.636	4.00	0.914	0.149
		IN-JX915		N EU	6.636	5.00	1.832*	0.130
				S EU	6.636	4.00	1.832	0.130
		IN-R3273		N EU	6.636	5.00	2.576*	0.959
				S EU	6.636	4.00	2.288	0.851
		IN-KP533		N EU	6.636	5.00	1.791*	0.222
				S EU	6.636	4.00	1.477	0.181
		M5		N EU	6.636	5.00	0.776*	0.029
				S EU	6.636	4.00	0.776	0.029

* in **bold** worst-case values

Table 8.9-91: Actual and TWA of worst PEC_{SW} and PEC_{SED} for IN-U3204, IN-W3595 and IN-KQ960 (Step 2) on grape (late applications).

Method of calculation	FOCUS Step 2
Application rate	5 x 0.45 kg product/ha
Scenario	worst case scenario for each metabolite (late applications, Central Europe)

PEC _(sw)		IN-U3204				IN-W3595				IN-KQ960			
Worst case		Vine, late application, Central EU*				Vine, late application, Central EU*				Vine, late application, Central EU*			
		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.811	-	0.026	-	0.690	-	0.055	-	2.249	-	0.114	-
Short term	24h	0.140	0.476	0.005	0.015	0.544	0.617	0.050	0.052	2.212	2.231	0.112	0.113
	2d	0.025	0.279	0.001	0.009	0.432	0.553	0.040	0.048	2.180	2.214	0.110	0.112
	4d	0.003	0.144	< 0.001	0.005	0.683	0.501	0.025	0.040	2.117	2.181	0.107	0.110
Long term	7d	< 0.001	0.083	< 0.001	0.003	0.341	0.498	0.012	0.031	2.027	2.134	0.103	0.108
	14d	< 0.001	0.041	< 0.001	0.001	0.068	0.334	0.003	0.018	1.829	2.030	0.093	0.103
	21d	< 0.001	0.028	< 0.001	0.001	0.013	0.234	0.001	0.013	1.651	1.933	0.084	0.098
	28d	< 0.001	0.021	< 0.001	0.001	0.003	0.178	< 0.001	0.010	1.491	1.842	0.075	0.093
	42d	< 0.001	0.014	< 0.001	0.001	< 0.001	0.118	< 0.001	0.006	1.215	1.678	0.061	0.085
	50d	< 0.001	0.012	< 0.001	< 0.001	< 0.001	0.099	< 0.001	0.005	1.081	1.593	0.055	0.081
	100d	< 0.001	0.006	< 0.001	< 0.001	< 0.001	0.050	< 0.001	0.003	0.520	1.180	0.026	0.060

* worst case scenario. All the other scenarios were simulated and will be provided under request.

Table 8.9-92: Actual and TWA of worst PEC_{SW} and PEC_{SED} for IN-T4226, IN-JX915 and IN-R3273 (Step 2) on grape (late applications).

Method of calculation	FOCUS Step 2
Application rate	5 x 0.45 kg product/ha
Scenario	worst case scenario for each metabolite (late applications, Central Europe)

PEC _(sw)		IN-T4226				IN-KX915				IN-R3273			
Worst case		Vine, late application, Central EU*				Vine, late application, Central EU*				Vine, late application, Central EU*			
		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		1.088	-	0.180	-	1.832	-	0.130	-	2.576	-	0.959	-
Short term	24h	0.935	1.011	0.165	0.173	1.202	1.517	0.087	0.108	2.290	2.433	0.860	0.910
	2d	0.804	0.940	0.142	0.163	0.800	1.259	0.058	0.090	2.051	2.302	0.770	0.862
	4d	0.595	0.818	0.105	0.143	0.477	0.922	0.051	0.073	1.646	2.073	0.618	0.777
Long term	7d	0.378	0.673	0.067	0.118	0.140	0.646	0.015	0.055	1.183	1.786	0.444	0.670
	14d	0.132	0.454	0.023	0.080	0.008	0.346	0.001	0.030	0.548	1.306	0.206	0.490
	21d	0.046	0.330	0.008	0.058	0.001	0.232	< 0.001	0.020	0.254	0.998	0.095	0.374
	28d	0.016	0.254	0.003	0.045	< 0.001	0.174	< 0.001	0.015	0.117	0.793	0.044	0.297
	42d	0.002	0.172	< 0.001	0.030	< 0.001	0.116	< 0.001	0.010	0.025	0.549	0.009	0.206
	50d	< 0.001	0.144	< 0.001	0.025	< 0.001	0.097	< 0.001	0.008	0.010	0.463	0.004	0.146
	100d	< 0.001	0.072	< 0.001	0.013	< 0.001	0.049	< 0.001	0.004	< 0.001	0.233	< 0.001	0.087

* worst case scenario. All the other scenarios were simulated and will be provided under request

Table 8.9-93: Actual and TWA of worst PEC_{SW} and PEC_{SED} for IN-KP533 and M5 (Step 2) on grape (late applications).

Method of calculation	FOCUS Step 2
Application rate	5 x 0.45 kg product/ha
Scenario	worst case scenario for each metabolite (late applications, Central Europe)

PEC _(sw)		IN-KP533				M5			
Worst case		Vine, late application, Central EU*				Vine, late application, Central EU*			
		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]		PEC _{SW} [µg a.s./L]		PEC _{SED} [µg a.s./kg dry sediment]	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		1.791	-	0.222	-	0.776	-	0.029	-
Short term	24h	1.371	1.581	0.177	0.199	0.470	0.623	0.018	0.023
	2d	1.050	1.396	0.163	0.178	0.286	0.500	0.011	0.019
	4d	0.616	1.107	0.080	0.142	0.106	0.343	0.006	0.013
Long term	7d	0.277	0.816	0.036	0.105	0.024	0.220	0.001	0.009
	14d	0.043	0.471	0.006	0.060	0.001	0.113	< 0.001	0.005
	21d	0.007	0.321	0.001	0.041	< 0.001	0.076	< 0.001	0.003
	28d	0.001	0.241	< 0.001	0.031	< 0.001	0.057	< 0.001	0.002
	42d	< 0.001	0.161	< 0.001	0.021	< 0.001	0.038	< 0.001	0.002
	50d	< 0.001	0.135	< 0.001	0.017	< 0.001	0.032	< 0.001	0.001
	100d	< 0.001	0.068	< 0.001	0.009	< 0.001	0.016	< 0.001	0.001

* worst case scenario. All the other scenarios were simulated and will be provided under request

8.9.2.3 PEC_{sw/sed} of 'CYMOXANIL 33% + ZOXAMIDE 33% WG'

Calculation of PEC_{sw} for the formulation 'CYMOXANIL 33% + ZOXAMIDE 33% WG'

Due to the differing and unknown dissipation times of the constituents of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' in aquatic systems, it is only possible to calculate the maximum instantaneous PEC_{sw} value from entry through spray-drift that occurred immediately after single and multiple applications for each crop/crop group.

For single applications the PEC_{sw} was calculated using the following equation:

$$PEC_{sw} (\mu g/L) = \frac{\% \text{ Drift}_{90th\%ile} \times \text{Application rate (g / ha)}}{\text{Water depth (cm)} \times 10}$$

For multiple applications the PEC_{sw} was calculated considering the actual rate after the last application based on following equation. Then, the concentration was calculated using the same equation as for single applications.

$$Application\ rate_n (\mu g/L) = \frac{Application\ rate (\mu g / L) \cdot (1 - e^{-nki})}{(1 - e^{-ki})}$$

where

Application rate	initial PEC in soil after single application	[mg/kg]
Application rate _n	initial PEC in soil after multiple application	[mg/kg]
n	number of applications	[-]
k	degradation rate in soil	[1/d]
i	application interval	[d]

The formulated product 'Cymoxanil 33% + Zoxamide 33% WG' is a water dispersible granule (WG) formulation containing 33% (w/w) of cymoxanil and 33% (w/w) of zoxamide as nominal active substance concentrations. PEC_{soil} of the formulated product was calculated for single and multiple applications

Single application values are considered relevant for the risk assessment; multiple applications and longer-term PECs are better described by active substance data. However, as an (unrealistic) worst-case assumption also PECs for multiple applications considering a half-life of 6.4 days for degradation between applications. This value was taken from the slower degrading compound zoxamide.

Drift entries were calculated with the FOCUS SWASH drift calculator.

As a result, the following PEC_{sw} values were obtained for a standard 30 cm high FOCUS ditch. Drift reduction nozzles were not considered for single applications since they never represent the worst-case situation.

Table 8.9-94: PEC_{sw} for the formulation ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ assuming drift entries

Crop	Rate (g/ha)		Single application	Multiple applications			
		Drift reduction	0 %	0 %	50 %	75 %	90 %
		Buffer distance [m]	PEC _{sw} [µg/L ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’] *				
Vine early	3*450	3 m (standard)	2.5776	3.9759	1.9880	0.9940	0.3976
		10 m	0.5409	0.7465	0.3732	0.1866	0.0746
		20 m	0.1842	0.2355	0.1177	0.0589	0.0235
Vine late	3*450	3 m (standard)	7.7595	11.1922	5.5961	2.7980	1.1192
		10 m	1.6994	2.4040	1.2020	0.6010	0.2404
		20 m	0.5961	0.8321	0.4160	0.2080	0.0832
Potato	3*450	1-2 m (standard)	2.8911	3.5584	1.7792	0.8896	0.3558
		5 m	0.8286	0.9417	0.4708	0.2354	0.0942
		10 m	0.4157	0.4938	0.2469	0.1234	0.0494

* taking into account a DegT₅₀ of 6.4 days (whole system) for zoxamide

Table 8.9-95: PEC_{sw} for the formulation ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ assuming drift entries

Crop	Rate (g/ha)		Single application	Multiple applications			
		Drift reduction	0 %	0 %	50 %	75 %	90 %
		Buffer distance [m]	PEC _{sw} [µg/L ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’] *				
Vine early	3*450	3 m (standard)	2.5776	3.9759	1.9880	0.9940	0.3976
		10 m	0.5409	0.7465	0.3732	0.1866	0.0746
		20 m	0.1842	0.2355	0.1177	0.0589	0.0235
Vine late	3*450	3 m (standard)	7.7595	11.1922	5.5961	2.7980	1.1192
		10 m	1.6994	2.4040	1.2020	0.6010	0.2404
		20 m	0.5961	0.8321	0.4160	0.2080	0.0832
Potato	3*450	1-2 m (standard)	2.8911	3.5584	1.7792	0.8896	0.3558
		5 m	0.8286	0.9417	0.4708	0.2354	0.0942
		10 m	0.4157	0.4938	0.2469	0.1234	0.0494

* taking into account a DegT₅₀ of 6.4 days (whole system) for zoxamide

Long-term predicted environmental concentrations (PEC values) were calculated for the active substances contained in the formulation. The impact of formulants is limited to short-term effects, such as formation of stable spray dispersions or to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution, is negligible. Therefore, for the purposes of this risk assessment, it is assumed that formulants do not influence the fate and behaviour of the active substances in the environment; they are not considered further.

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

Zoxamide

Table 8.10-1: Summary of atmospheric degradation and behaviour

Compound	Zoxamide
Direct photolysis in air	Not studied, no data necessary.
Quantum yield of direct phototransformation	(Φ) = 0.0225 ($\lambda > 290$ nm)
Photochemical oxidative degradation in air	DT ₅₀ (h): 7.5; derived by Atkinson calculation method, assuming a hydroxyl radical concentration of 1.5×10^6 OH/cm ³ and a 12 hour day. Rate constant for reaction with hydroxyl radicals: 17.1×10^{-12} cm ³ /(molecule sec.)
Volatilisation	Vapour pressure (Pa): 1.3×10^{-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 1.3×10^{-5} Pa. Thus, according to EVA 3.2h 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.

Cymoxanil

Table 8.10-2: Summary of atmospheric degradation and behaviour

Compound	Cymoxanil
Quantum yield of direct phototransformation	0.0052 / 0.00058 (n = 2)
Photochemical oxidative degradation in air	DT50 of 21.3 hrs derived by the Atkinson model (version 1.91), OH- concentration (12-hrs day) assumed = 1.5×10^6 cm ⁻³
Volatilisation	Vapour pressure (Pa): 1.5×10^{-4} Henry's Law Constant (Pa.m ³ /mol): 3.244×10^{-5}

Cymoxanil has low volatility, as indicated by a low vapour pressure of 1.5×10^{-4} Pa. The Henry's law constant was calculated to be 3.244×10^{-5} Pa x m³ x mol⁻¹. Calculations according to the method of Atkinson for indirect photo-oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 21.3 hours, indicating that the small proportion of applied Cymoxanil that will volatilise would be unlikely subject to long range atmospheric transport.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1.1 (KCA 7.1.1)	Derz, K.	2020	Aerobic degradation of RH-24549 in three soils according to the OECD 106 Gowan Crop Protection Ltd., UK Fraunhofer IME, Germany, Report No. MKC-004/5-30 GLP Not published	N	GW I
KCP 9.1.1.1 (KCA 7.1.1)	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	N	GW I
KCP 9.1.1.1 (KCA 7.1.1.)	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	N	GW I
KCP 9.1.1.1	Clark, B.	2010a	¹⁴ C-IN-KQ960: Rate of degradation in five soils ABC Laboratories, Inc. Columbia, Missouri. USA, report no. Du Pont 28466/ ABC 65143 GLP Not published	N	Sipcam Oxon S.p.A / DuPont

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
			AIIA study on the active substance Cymoxanil		
KCP 9.1.2	Clark, B.	2010b	¹⁴ C-IN-KQ960: Batch equilibrium (adsorption/desorption) in five soils ABC Laboratories Inc. Columbia, Missouri. USA Report No. DuPont 28467/ ABC 65144 GLP Not published AIIA study on the active substance Cymoxanil	N	Oxon Italia S.p.A / DuPont
KCP 9.2.5	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	N	GW I
KCP 9.2.5	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 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S16-05375 GLP Not published	N	GW I
KCP 9.2.5	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 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S19-01450 GLP Not published	N	GW I
KCP 9.2.5	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 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S16-05376 GLP Not published	N	GW I

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.5	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 Italy in 2020 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S19-23773 GLP Not published	N	GW
KCP 9.2.5	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 No GLP Not published	N	GW

SIPCAM Oxon S.p.A. is the legal successor of Oxon Italia S.p.A.; Gowan Crop Protection (GW) is the legal entity of the company Gowan in Europe

Green shaded = confirmatory-like studies which are under evaluation by the RMS for Zoxamide in an interzonal procedure.

Grey shaded = data / reference already provided during product authorisation

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	14C-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	GW

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	Smalley, J, Reynolds, JL	1997	Aerobic soil metabolism of [14C]-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	GW I
KCA 7.1.1.2	Kim-Kang, H	1997	Anaerobic soil metabolism of [14C]-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	GW I
KCA 7.1.1.2	Volkel, W	1998	14C-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	GW I
KCA 7.1.1.3	Reynolds, JL	1997	Soil photolysis of [14C]-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	GW I
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	GW I
KCA 7.1.2.1.1	Burgener, A	1998	14C-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	GW I

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 7.1.2.1.1	Smalley, J, Reynolds, JL	1997	Aerobic soil metabolism of [14C]-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	GWl
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	GWl
KCA 7.1.2.1.2	Van den Bosch, M.M.H.	2013	Determination of the aerobic degradation rate of RH-141,455 in soil WIL Research Europe B.V., The Netherlands, Report No. 500850 GLP Not published	N	GWl
KCA 7.1.2.1.3	Kim-Kang, H	1997	Anaerobic soil metabolism of [14C]-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	GWl
KCA 7.1.2.1.3	Volkel, W	1998	14C-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	GWl
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	GWl

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	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	GWl
KCA 7.1.3.1.2	Reynolds, J.L.	1998	Adsorption and desorption of 14C-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	GWl
KCA 7.1.3.1.2	Volkel, 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	GWl
KCA 7.1.3.1.2	Volkel, W.	1998	Determination of the Adsorption Coefficient of 14C-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	GWl
KCA 7.1.3.1.2	Volkel, 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	GWl
KCA 7.1.4.1.2	Volkel, W.	1998	14C-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	GWl

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 7.2.1.1	Reynolds, J.L.	1998	Hydrolysis of [14C]-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	GWl
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	GWl
KCA 7.2.1.2	Smalley, J. and Reynolds, J.L.	1998	Aqueous photolysis of [14C]-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	GWl
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 GLP Not published	N	GWl
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	GWl
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	GWl

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 7.2.2.3	Morgenroth, U	1998	14C-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	GW
KCA 7.3.2	Burgener, A	1998	Investigation of the volatilization of 14C-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	GW

GW = Gowan Crop Protection Ltd.

For cymoxanil it is referred to the references in the EU review dossier (DAR 2007) and the EFSA Peer Review Conclusion (2008).

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 RH-24549

The following study has been provided to Latvia as RMS for zoxamide and cMSs for interzonal evaluation in July 2020.

Comments of zRMS:	<p>This study conducted in accordance with OECD 307 guidance and GLP requirements.</p> <p>The aerobic degradation of RH-24549 to RH-141455. The kinetic models SFO, FOMC, HS and DFOP were taken into consideration. The proposed endpoints were calculated: RH-24549. $DT_{50} = 10.9$ d; RH-141455. $DT_{50} = 2.4$ d; The formation fraction $ff = 0.505$.</p> <p>The new study was conditionally accepted for zonal assessment and the endpoints were used in exposure assessment. The final decision of study acceptance will be made at the EU level.</p>
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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.

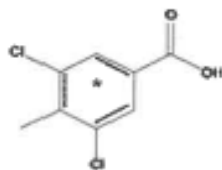
Materials and methods

A. Materials

1. Test material

[phenyl- ^{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 2-1: 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 H₂O/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 2-2: 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 $20 \pm 2^\circ\text{C}$ 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 glass 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 $20 \pm 2^\circ\text{C}$.

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).

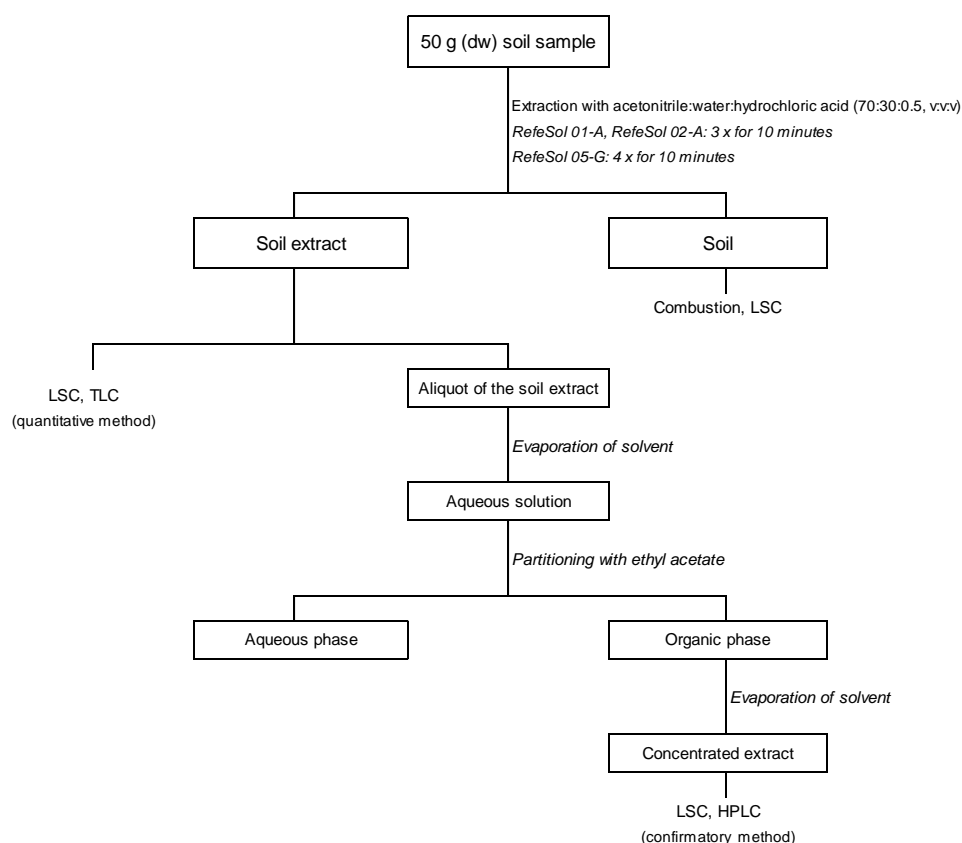


Figure A 2: Sample preparation scheme

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 $^{14}\text{CO}_2$ 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)

Instrument

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 Valuation 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 $^{14}\text{CO}_2$ 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 $^{14}\text{CO}_2$), 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 2-3: 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 ($\mu\text{g C/g soil}$)	205	--	--	--	--	--	--	--	--
Soil RefeSol 05-G									
Days after application	0	2	4	8	15	22	36	50	80
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 ($\mu\text{g C/g soil}$)	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 2-4: Results of CAKE calculations for the RH-24549

Soil	Kinetics	chi ²	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

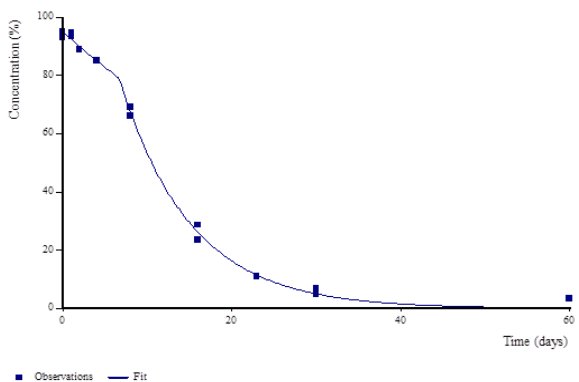
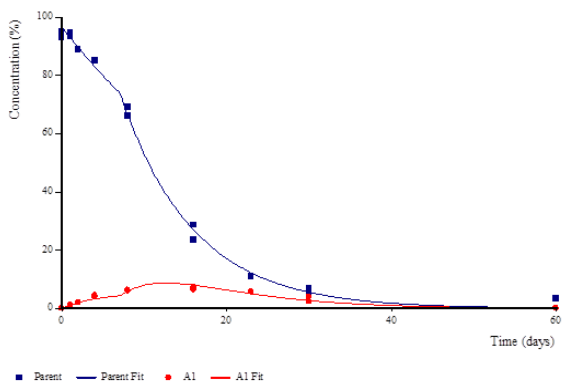
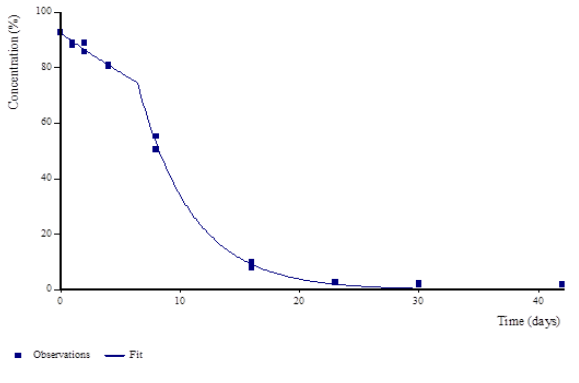
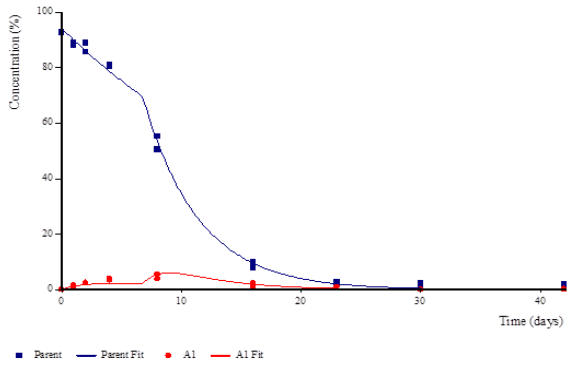
For RefeSol 05-G two CAKE calculations were carried out: one calculation including all sampling dates (0 days – 80 days, “extended”) and one calculation including all sampling dates except 80 days (0 days – 50 days). The reason was the difference in the distribution of radioactivity found in the extracts 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.

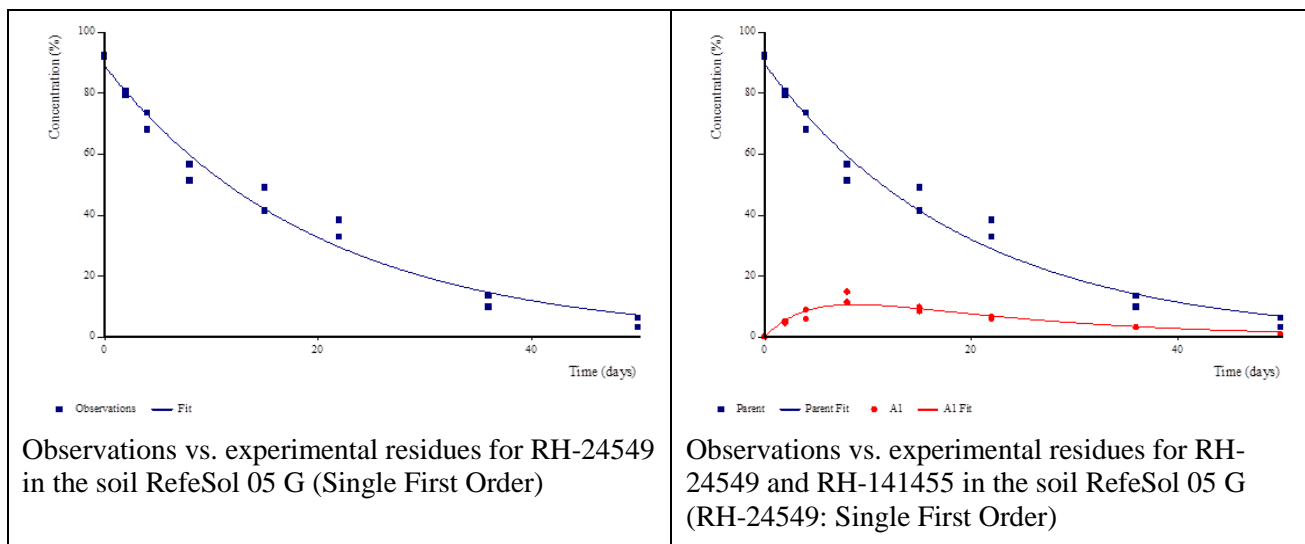
The residues of the transformation product RH-141455 were calculated including its formation fractions. The analysis for the metabolite RH-141455 was based on the best fit kinetics for the parent compound, for the metabolite always SFO degradation was considered.

Table A 2-5: Results of CAKE calculations for the metabolite RH-141455

Soil	Kinetics	chi ²	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 DT₅₀ of 2.4 days and an arithmetic mean formation fraction of 0.505 (n=3) were calculated.

RH-245489	RH-141455
The figures show the fitted model together with the experimental residues.	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.
 <p>Observations vs. experimental residues for RH-24549 in the soil RefeSol 01 A (Hockey Stick)</p>	 <p>Observations vs. experimental residues for RH-24549 and RH-141455 in the soil RefeSol 01 A (RH-24549: Hockey Stick)</p>
 <p>Observations vs. experimental residues for RH-24549 in the soil RefeSol 02 A (Hockey Stick)</p>	 <p>Observations vs. experimental residues for RH-24549 and RH-141455 in the soil RefeSol 02 A (RH-24549: Hockey Stick)</p>



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.

(Derz K. 2020)

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

The following study has been provided to Latvia as RMS for zoxamide and cMSs for interzonal evaluation in July 2020.

Comments of zRMS:	The recalculation report including new DT_{50} values was accepted. The normalized DT_{50} values for metabolites RH-24549 and RH-141455 were presented and conditionally were used in further assessment. The final decision of study acceptance will be made at the EU level.
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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), Schmallingenberg, 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:

$$DegT_{50}(pF2) = DegT_{50} (exp) \left(\frac{Moisture(exp)}{Moisture (pF2)} \right)^{0.7}$$

DegT₅₀(exp): exp. DegT₅₀ (d)
 DegT₅₀(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 2-6: 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 2-7: 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 DegT₅₀ 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 DegT₅₀ values were in the range of 0.89 to 3.22 days.

Considering the evaluated soil degradation values of EFSA (2017) and the normalised DegT₅₀ values (20°C, pF2) of the new study of Derz (2020), overall geometric mean DegT₅₀ 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 2-8: 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	Evaluated 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	n (Derz, 2020)
RefeSol 01-A	sandy loam	5.7	20	45	11	24.6	8.52	2.22	HS	
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	n
Geometric mean (n=7)							6.84			
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 [¹⁴C]-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 2-9: Results of CAKE calculations for the metabolite RH-141455

RH-141455, laboratory studies, aerobic conditions											
Soil name or location	Soil type	pH	T (°C)	MWH C (%)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 0°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	--	

RH-141455, laboratory studies, aerobic conditions											
Soil name or location	Soil type	pH	T (°C)	MWH C (%)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 0°C & pF2	Chi ² (%)	Kinetic model	FF	Evaluated on EU level y/n/ Reference
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)

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 calculated from a study with the parent compound zoxamide; length of DT₅₀ mainly due to low detections

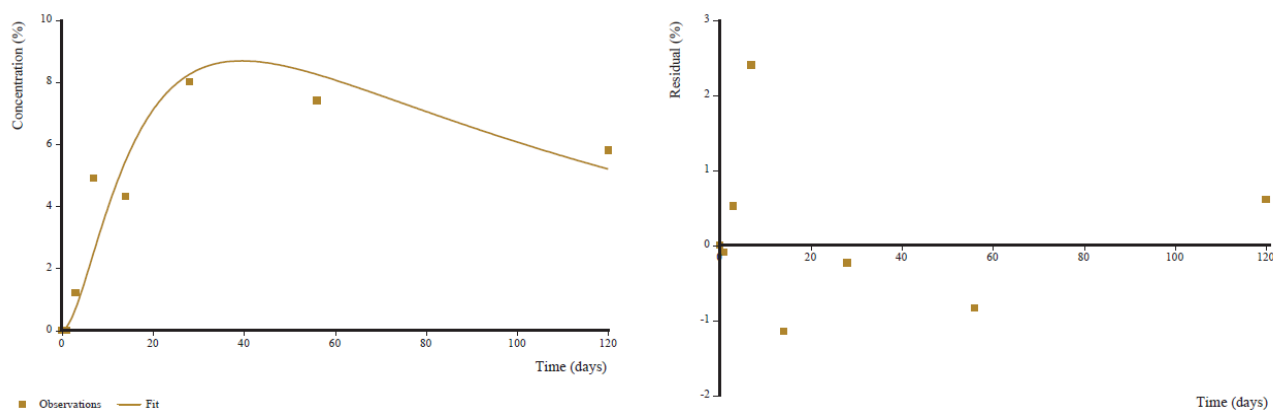
³ study conducted with RH-141455

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 DT₅₀ 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)³² 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 chi² % 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) DegT₅₀ value for this metabolite were markedly affected by its low residue values especially at the final time-points of the Burgener (1998) study.



³² 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 3: 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 DT₅₀ and DT₉₀ values were calculated according to the FOCUS (2006, 2011³³). They amounted to 12.0 days (SFO, DT₉₀ of 40.0 days) for Speyer 2.2, 11.1 days for Speyer 2.3 (SFO, DT₉₀ of 36.9 days) and 31.7 days for Speyer 6S (SFO, DT₉₀ of 105.3 days). The related DegT₅₀ at standard reference conditions (pF2, 20°C) range from 9.54-14.72 days. This is longer compared to studies of Derz (2020) with DegT₅₀ 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 (2014³⁴) are the same: visual assessment and chi² statistics. For both the parent and the metabolite the chi² statistics is calculated separately.

Ideally, the chi² 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 chi² 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 chi² error of parent is smaller than 3 %.

³³ FOCUS (2011): Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration, version 1.0, November 2011

³⁴ FOCUS (2014): Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration, version 1.1, December 2014

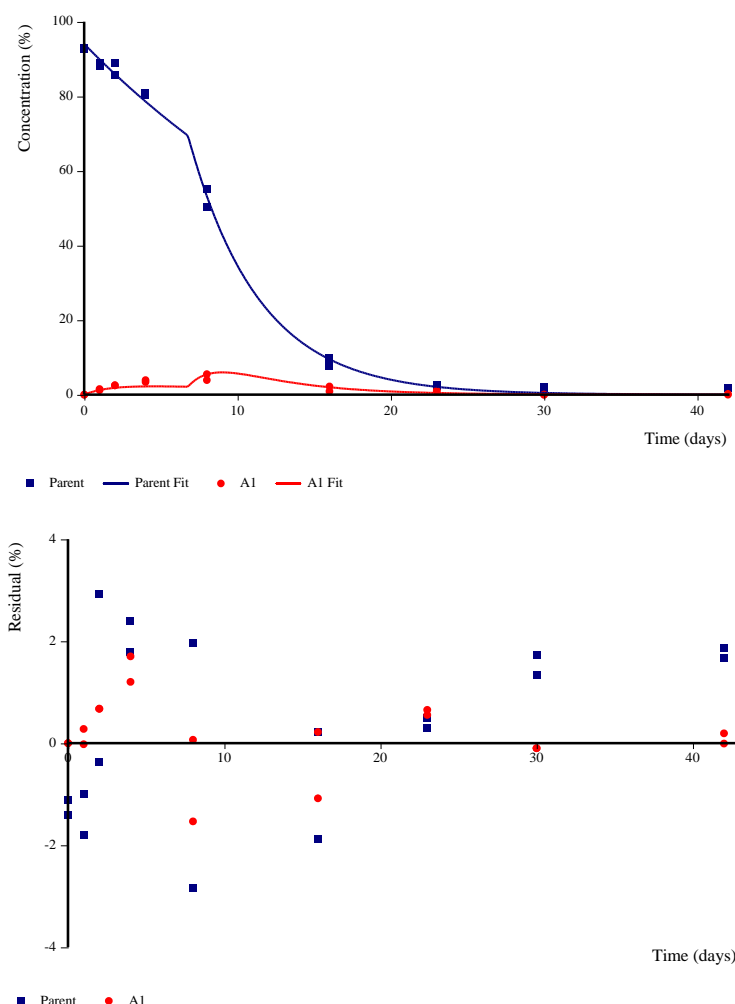


Figure A 4: Plot of the decline and the residuals of RH-24549 and RH-141455 from the silt loam RefeSol-02 A, using HS kinetics for RH-24549 and SFO for RH-141455 (see Derz 2020)

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 χ^2 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 χ^2 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 DegT₅₀ values (20°C, pF2) for RH-24549 were found in the range of 6.83 to 14 days. For RH-141455 the respective normalised DegT₅₀ values were in the range of 0.89 to 3.22 days.

Considering the evaluated soil degradation values of EFSA (2017) and the normalised DegT₅₀ values (20°C, pF2) of the new study of Derz (2020), overall geometric mean DegT₅₀ 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 [¹⁴C]-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.

(Klein J. & Mendel-Kreusel R. 2020)

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.*

The following study has been provided to Latvia as RMS for zoxamide and cMSs for interzonal evaluation in July 2020.

Comments of zRMS:	<p>The new study was conditionally accepted up to final decision at interzonal level. (R)-Zoxamide and (S)-Zoxamide were degraded rapidly in soil and both represented only 4.8% of the applied test item (ATI) after 29 days of aerobic incubation. The calculated SFO DT₅₀ values of 4.7 - 5.2 days.</p> <p>Metabolites RH-127450 and RH-163353 were detected. RH-127450 reached a maximum of 12.0% ATI on day 7 and degraded thereafter to 1.3% ATI after 29 days of aerobic incubation. No difference between the enantiomers was detected. The calculated SFO DT₅₀ values of 5.0 - 7.5 days RH-163353 reached a maximum of 3.4% ATI on day 7 and degraded thereafter to 0.4% ATI after 29 days of aerobic incubation. he calculated SFO DT₅₀ of 9.6 days.</p> <p>No difference in rate of degradation of both (R)- and (S)-enantiomers was observed. The ratio of the enantiomers was nearly 1:1 at each sampling interval</p>
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	for parent and metabolite RH-127450.
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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 DT₉₀ 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-methylacetyl)-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 2-10: 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 H₂O/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 2-11: Microbial biomass determined by means of SIR-method described by Anderson and Domsch³⁵

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 H₂O/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/cm³), the concentrations of the isomers of zoxamide and its degradation products in soil were followed over a period of 29 days (i.e. when DT₉₀ for zoxamide was reached).

³⁵ 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

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.

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 2-12: 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 2-13: 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 DT₅₀/DT₉₀ values and formation fractions

Based on the achieved experimental data, rate constants and DT₅₀/DT₉₀ 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 2-14: Results of CAKE calculations for zoxamide and its metabolites

Substance	Kinetics	chi ²	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

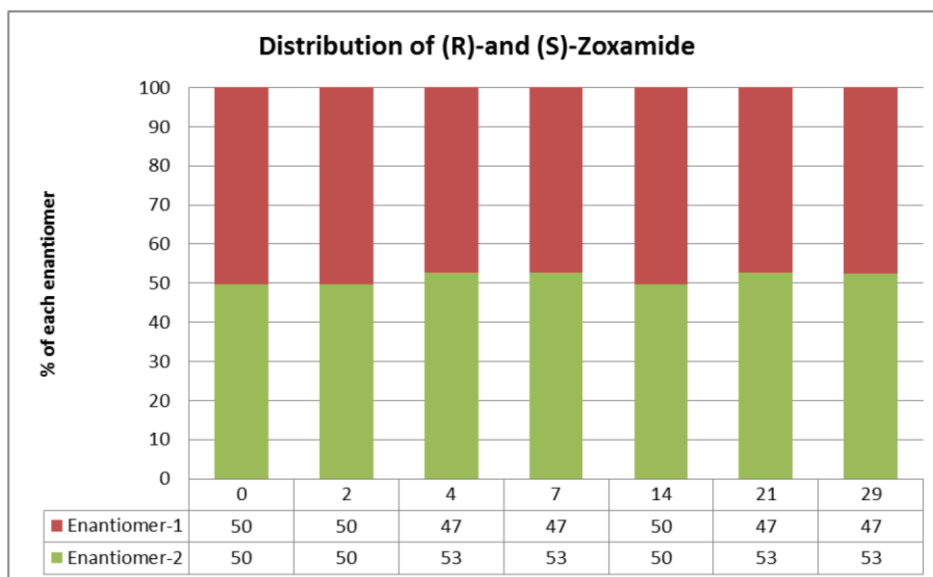


Figure A 5: Distribution of (R)- and (S)-Zoxamide over all sampling intervals

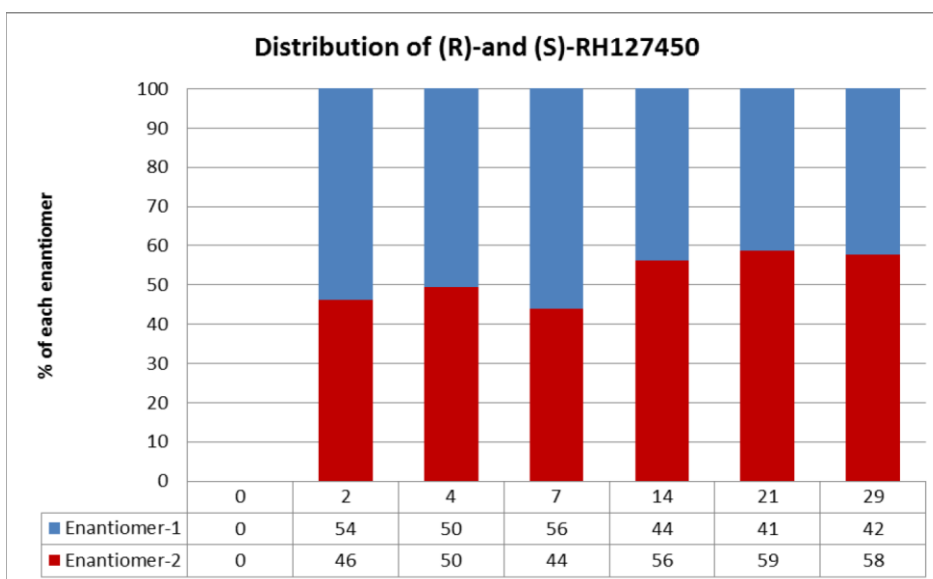
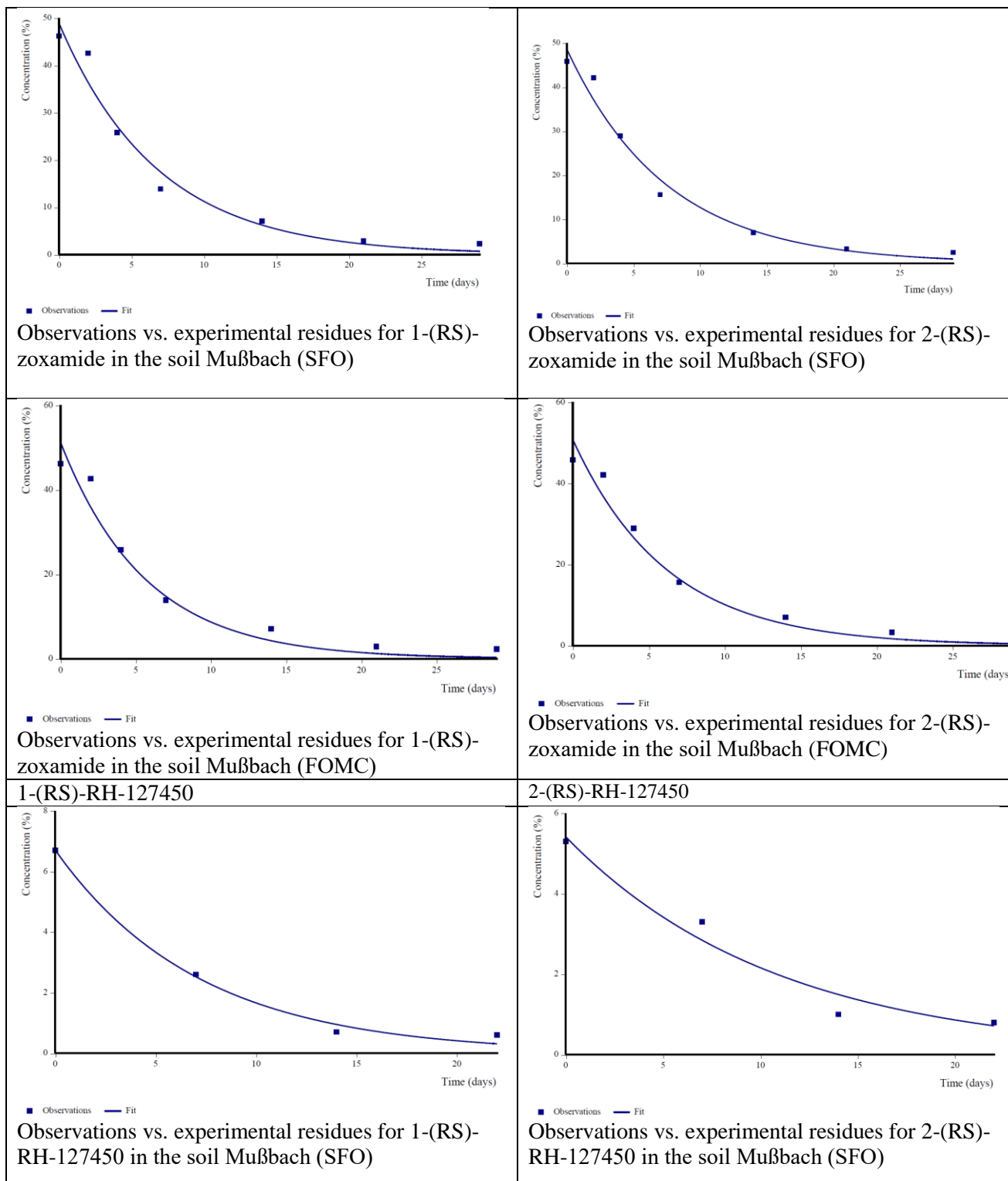
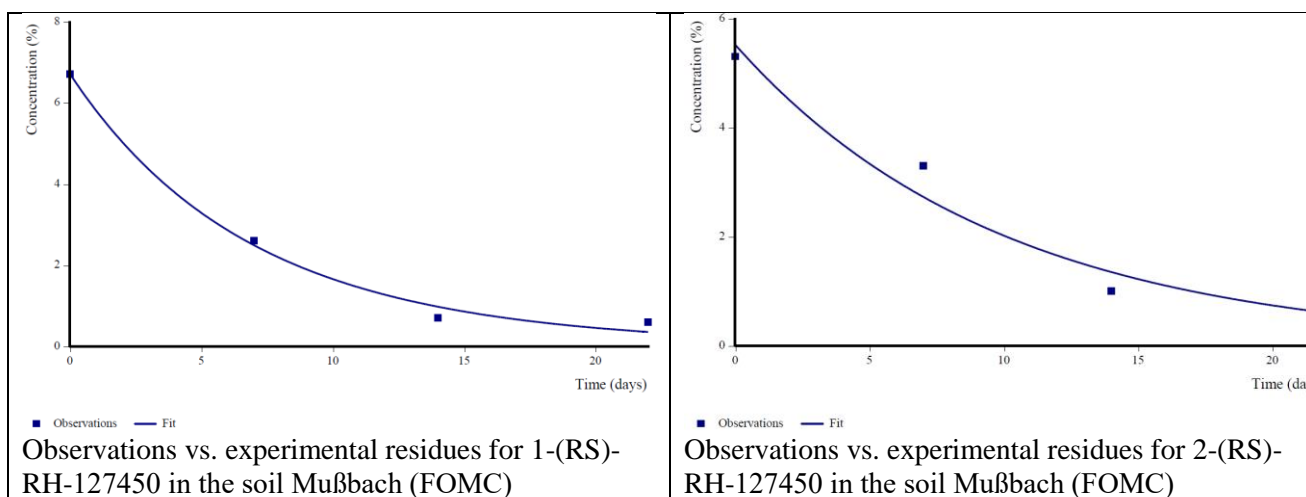


Figure A 6: Distribution of (R)- and (S)-RH-127450 over-all sampling intervals

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





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 DT₅₀ values of 4.7 - 5.2 days. The enantiomers of RH-127450 degraded also rapidly in soil under aerobic conditions with similar calculated SFO DT₅₀ values of 5.0 - 7.5 days. No separation of the RH-163353 enantiomers was achieved. RH-163353 degraded rapidly with a calculated SFO DT₅₀ of 9.6 days.

(Kercher S. 2017)

A 2.4 Study 4

This document is for the renewal of the authorisation of product Cymoxanil 33% + Zoxamide 33% WG according to article 43 of Regulation (EC) No 1107/2009, following the active substance renewal of zoxamide according to EU Regulation 2018/692. The data and information on cymoxanil are not concerned here.

The below cymoxanil studies have already been evaluated during product authorisation. The following summary information contains the consolidated information of the previous assessment related to cymoxanil - which does not require a re-evaluation at this stage / within this submission.

Reference:	KCP 9.1.1.1/04
Report	C-IN-KQ960: Rate of Degradation in Five Soils, Clark B., 2010a
Guideline(s):	Yes, OECD 307
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The aerobic biotransformation of radiolabeled IN-KQ960 was studied in 5 soils under aerobic conditions. The soils were chosen in order to represent a wide range of organic matter content (1.3-4.3%) and pH values (4.9-7.7).

The soils were treated with [Imidazazolidine-4-¹⁴C]IN-KQ960 at a concentration of 1.5 µg a.i./g dry weight soil, incubated at darkness at 20 ± 2°C, under aerobic in flow-through system to maintain soil moistures at 50%. The flow through systems were designed to trap evolved carbon dioxide (CO₂) and volatile organic compounds. Soil samples were extracted with a mixture of aqueous and organic solvents at 0, 1, 2, 3, 7, 14 and 21 days after treatment and analysed.

Results and discussions

The mean recovery of total radioactivity was 92.5% to 103.9% of the applied radioactivity for all soils. Mean extractability values were at 94.0% to 99.3% AR at day 0 in five soils, then decreased to a minimum of 0.2% AR (day 14), 6.1% AR (day 7), 1.7% AR (day 21), 2.8% (day 14) and 5.2% AR (day 7). As the level of extractable radioactivity decreased, the level of unextractable residue slowly increased during the course of the study.

During the course of the study the amount of [¹⁴C]IN-KQ960 in the extract decreased from an average of 96.2% at Day 0 to < 1% AR by Day 14 in Speyer 2.2 soil, 94.0% to 6.1% AR by Day 7 in the Tama soil, 97.9% to 1.7% AR by Day 21 in the Lleida soil, 97.3% to 2.8% AR at Day 14 in the Nambsheim soil and 99.3% to 5.2% AR at the Day 7 in the Sassafras soil.

The DT₅₀ and DT₉₀ values for IN-KQ960 were calculated by single first order (SFO) model and first-order multiple compartment (FMOC) model using ModelMaker 4.0. The SFO provided both a good visual and statistical fit for all soils and the FMOC model did not provide a better fit.

The DT₅₀ and DT₉₀ values are summarized below:

Soil				IN-KQ960 First order rate constant [day ⁻¹]	IN-KQ960 DT ₅₀ [days]	IN-KQ960 DT ₉₀ [days]	R ²	Model
	Type	pH	OC (%)					
Speyer 2.2	Sand	6.0	3.3	0.262	2.6	8.8	0.997	SFO
Tama	Silty clay	6.4	4.3	0.347	2.0	6.6	0.995	SFO
Lleida	Clay loam	7.7	2.1	0.165	4.2	14	0.997	SFO
Nambsheim	Sandy loam	7.4	2.58	0.198	3.5	11.7	0.989	SFO
Sassafras	Sandy loam	4.9	1.3	0.324	2.1	7.1	0.991	SFO
Geometric mean					2.76	9.2	-	-

Conclusion

A DT₅₀ geometric mean value of 2.76d was calculated.

A 2.5 Study 5

Reference:	KCP 9.1.2/01
Report	¹⁴ C-IN-KQ960: Batch equilibrium (adsorption/desorption) in five soils, Clark, B, 2010b
Guideline(s):	Yes, OECD106
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The adsorption/desorption properties of ^{14}C -IN-KQ960 were investigated to assess its potential mobility in soil. The adsorption coefficients K_d , K_{om} and K_{oc} and the Freundlich adsorption isotherm parameters K_f , K_{fom} , K_{foc} and $1/n$ were calculated on three European and two North American soils. The different soils were chosen in order to represent a wide range of organic matter content (1.3-5.4%) and pH values (4.9-7.7).

One adsorption experiment was performed using the batch equilibrium method on the soils with five concentration of the test item in 0.01M CaCl_2 . A 1:1 soil to solution ratio was used in the test.

The sorption coefficients K_d , K_{om} and K_{oc} were calculated for each soil at each concentration of test substance

Results and discussions

A summary of the results is reported below.

Soil				K_d (mL/g)	K_{om} (mL/g)	K_{oc} (mL/g)
	Type	pH	OC%			
Gross-Umstadt	Loam	6.7	1.9	0.0507	2.7	4.6
Drummer	Clay loam	5.8	5.4	0.2473	4.6	7.9
Lleida	Clay loam	7.7	2.1	0.1187	5.7	9.7
Nembsheim	Sandy loam	7.4	2.8	0.0621	2.2	3.8
Sassfras	Sandy loam	4.9	1.3	0.0183	1.4	2.4

The values for the Freundlich adsorption isotherm parameters K_f , K_{fom} , K_{foc} and $1/n$ were derived from the linear form of the Freundlich equation. A summary can be found below.

Soil				K_f	K_{fom}	K_{foc}	$1/n$
	Type	pH	OC%				
Gross-Umstadt	Loam	6.7	1.9	0.0357	1.88	3.23	0.8270
Drummer	Clay loam	5.8	5.4	0.1747	3.23	5.56	0.8404
Lleida	Clay loam	7.7	2.1	0.1097	5.23	8.99	0.9602
Nembsheim	Sandy loam	7.4	2.8	0.0459	1.64	2.82	0.8500
Sassfras	Sandy loam	4.9	1.3	0.0178	1.37	2.36	1.0660

K_{oc} and $1/n$ (Freundlich exponent) values for IN-KQ960 obtained from study 65144 (Clark, 2010b)

End-Point	IN-KQ960
K_{oc}	5.13 ^A
$1/n$	0.97 ^A

^A geometric mean

Conclusion

A geometric mean value of 5.13 mL/g K_{oc} and 0.97 geometric mean value for Freundlich Exponent were calculated.

A 2.6 Study 6 – Residue dissipation of zoxamide on/in plants

Substance specific DT₅₀ 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.

Comments of zRMS:	<p>The study report was evaluated and accepted. Based on residual studies all relevant data could be used in kinetics assessment of zoxamide residues.</p> <p>Based on the evaluated field residues data, rate constants and DT₅₀ values for zoxamide were calculated using CAKE software. all relevant kinetics were taken into consideration. The DT₅₀ = 4.2 d was assessed (geometric mean for n=16); indoor and Southern European field condition and in dicotyledonous plants.</p>
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Reference: **KCP 9.2.5/01**

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)³⁶ 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) 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 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) 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

³⁶ 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.

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 2-15: 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

* Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC

Table A 2-16: 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

** Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC

Detailed information on the residues decline trials of Luciani (2012a,b), reports no. AGRI 013/12 GLP DEC and AGRI 014/12 GLP DEC, are summarised in Part B Section 7. For information on the analytical method validation, please refer to Part B Section 5.

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 χ^2 (X^2).
2. Additionally, the coefficient of determination (r^2) was used if no distinction could be made based on χ^2 .
3. Finally, the visual fit was considered if no distinction could be made based on χ^2 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 2-17: 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, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC	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
			FOMC	2.08	0.994	11.2	155

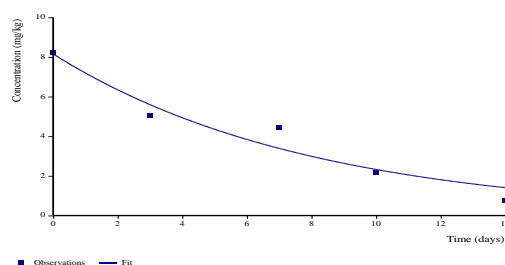
* Selected based on visual fit since no distinction could be found based on chi² and r² for DFOP and HS. The selection also represents the worst-case.

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 ($r^2 \geq 0.94$). 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.

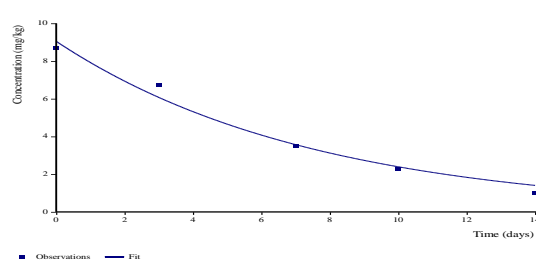
For lettuce Trocadero (1), lettuce Trocadero (2), lettuce Trocadero (3) and endive Quintana (1) minimum X^2 -values were found for SFO kinetics. The choice of kinetics was confirmed by the good visual fits (see Figure A 7:, demonstrating good visual fits for the best fit kinetics).

RA 12 058BPL IT 01

Lettuce Trocadero (1) (SFO)

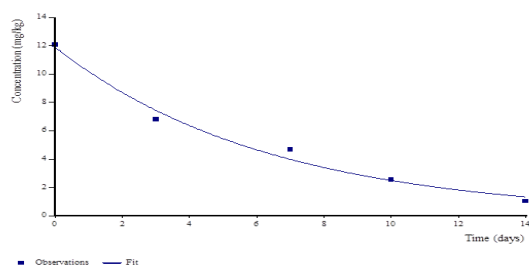


Lettuce Trocadero (2) (SFO)

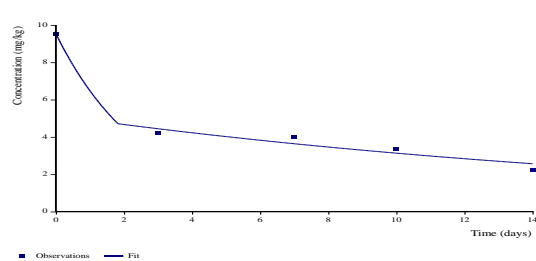


RA 12 058BPL IT 02

Lettuce Trocadero (3) (SFO)

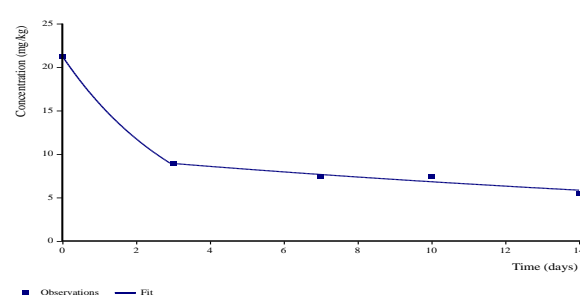


Lettuce Trocadero (4) (HS)

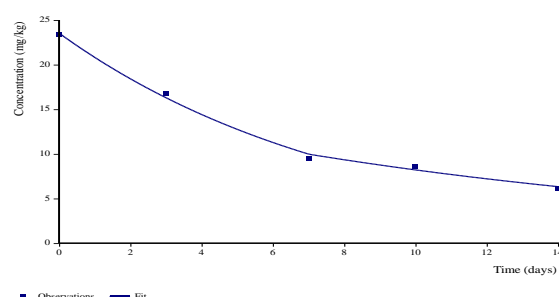


RA 12 058BPL IT 03

Rocket salad Selvatica (1) (HS)

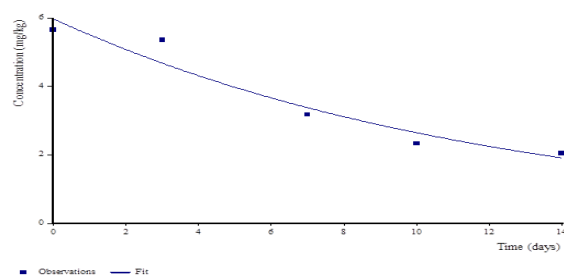


Rocket salad Selvatica (2) (HS)



RA 12 058BPL IT 04

Endive Quintana (1) (SFO)



Endive Quintana (2) (HS)

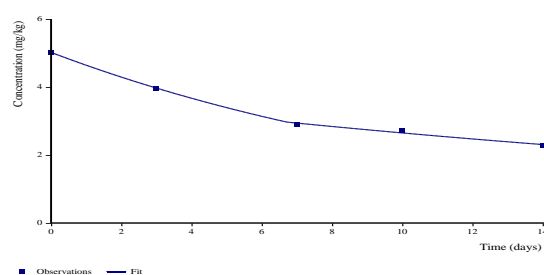


Figure A 7: Plot with the residue decline data of Zoxamide using the best fit kinetics for each salad variety - open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC

For Rocket salad Selvatica (1) and lettuce Trocadero (4) the kinetic models DFOP and HS are statistically even with respect to X^2 -statistics and the coefficient of determination. In Figure A 8: 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.

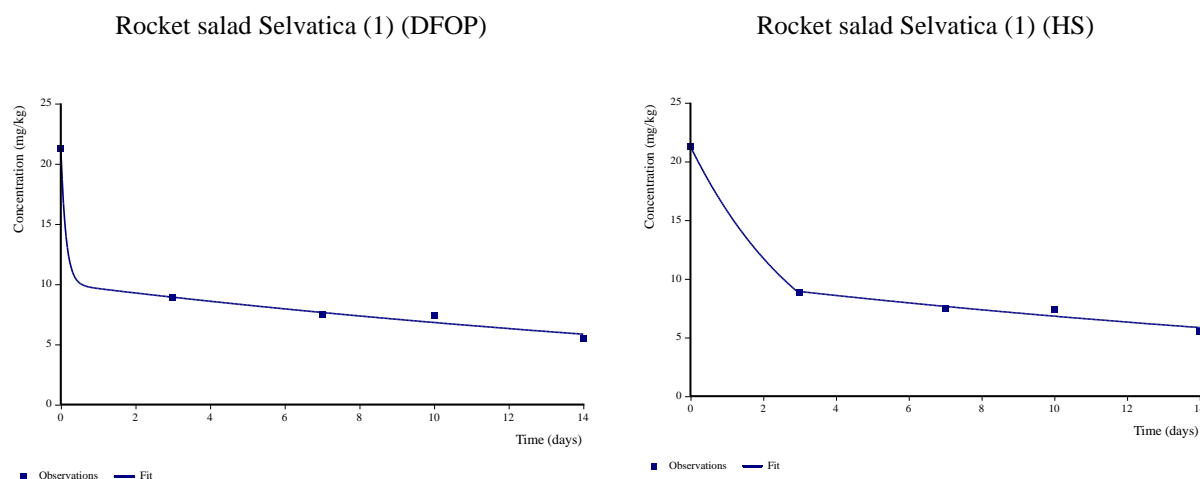


Figure A 8: Plot with the residue decline data of Zoxamide using the kinetic models DFOP (on the left side) and HS (on the right side) - rocket salad Selvatica (1), open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC

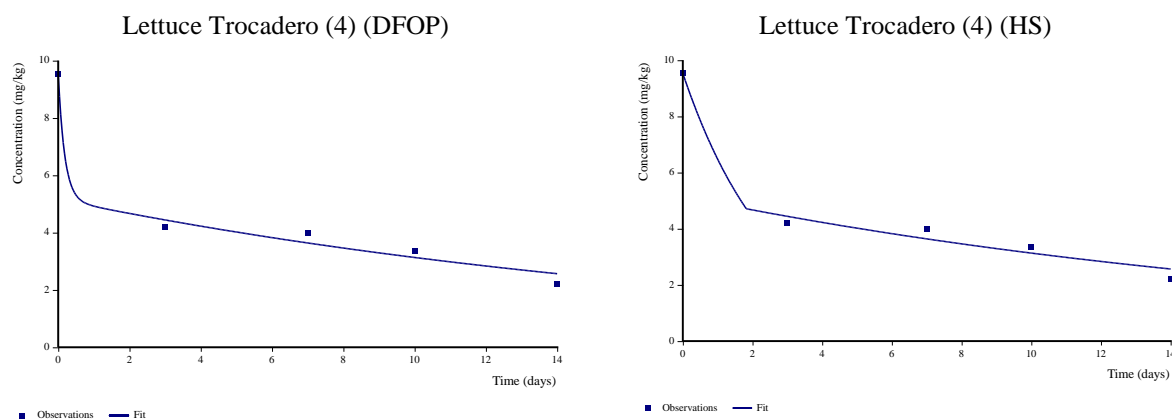


Figure A 9: Plot with the residue decline data of Zoxamide using the kinetic models DFOP (on the left side) and HS (on the right side) - lettuce Trocadero (4), open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC

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 2-18: Results of CAKE calculations for all kinetic models (open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC) - RA 12 058BPL IT 01, Lettuce Trocadero (1)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	5.53	5.53	5.53	5.53
DT₉₀ [days]	18.4	18.4	62.5	18.4
X² [%]	11.7	16.7	16.7	13.4
r²	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 CI (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 CI (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 2-19: Results of CAKE calculations for all kinetic models (open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC) - RA 12 058BPL IT 01, Lettuce Trocadero (2)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	5.22	5.22	5.22	5.21
DT₉₀ [days]	17.3	17.3	47.1	17.3
X² [%]	6.79	9.69	9.69	7.77
r²	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 CI (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 CI (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 2-20: Results of CAKE calculations for all kinetic models (open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC) - RA 12 058BPL IT 02, Lettuce Trocadero (3)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	4.44	4.08	4.59	4.31
DT₉₀ [days]	14.8	15.7	13.4	15.3
X² [%]	6.65	7.99	8.9	7.52
r²	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 CI (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 CI (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 2-21: Results of CAKE calculations for all kinetic models (open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC) - RA 12 058BPL IT 02, Lettuce Trocadero (4)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	6.01	1.59	1.79	2.38
DT₉₀ [days]	20	33.9	33.9	399
X² [%]	17.4	6.58	6.58	7.61
r²	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 CI (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 CI (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 2-22: Results of CAKE calculations for all kinetic models (open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC) - RA 12 058BPL IT 03, Rocket salad Selvatica (1)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	5.66	0.365	2.34	1.52
DT₉₀ [days]	18.8	40.4	40.4	973
X² [%]	19.9	3.63	3.63	4.01
r²	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 CI (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 CI (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	$\alpha = 0.625$ $\beta = 0.755$ 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 2-23: Results of CAKE calculations for all kinetic models (open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC) - RA 12 058BPL IT 03, Rocket salad Selvatica (2)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	6.54	5.84	5.66	5.95
DT₉₀ [days]	21.7	>10,000	29.3	30.1
X² [%]	5.25	5.28	3.46	4.55
r²	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	$\alpha = 2.134$ $\beta = 15.51$ M ₍₀₎ = 23.49
Lower CI (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	$\alpha = -6.473$ $\beta = -63.28$ M ₍₀₎ = 19.18
Upper CI (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	$\alpha = 10.74$ $\beta = 94.29$ 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 2-24: Results of CAKE calculations for all kinetic models (open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC) - RA 12 058BPL IT 04, Endive Quintana (1)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	8.53	8.53	8.2	8.53
DT₉₀ [days]	28.3	28.3	125	28.4
X² [%]	8.14	11.6	11.4	9.31
r²	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	$\alpha = 213.7$ $\beta = 2620$ M ₍₀₎ = 5.969
Lower CI (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	$\alpha = -1852$ $\beta = -22690$ M ₍₀₎ = 3.738
Upper CI (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	$\alpha = 2280$ $\beta = 27900$ 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 2-25: Results of CAKE calculations for all kinetic models (open field, Southern EU, Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC) - RA 12 058BPL IT 04, Endive Quintana (2)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	11.4	11.1	11.6	11.2
DT₉₀ [days]	37.8	>10,000	58.2	155
X² [%]	4.07	2.32	1.09	2.08
r²	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 CI (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 CI (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 (X²).

Table A 2-26: Results of CAKE calculations for all kinetic models - Zoxamide residue dissipation data on/in salad plants indoor

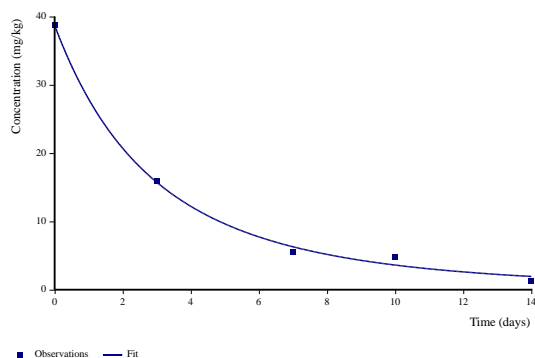
	Field trial no.	Crop	Kinetics	X ² [%]	r ²	DT ₅₀ [d]	DT ₉₀ [d]
Open field, Southern EU, Luciani G.P. 2012, report no. 12058BPL IT 04	R03AG12-01	Lettuce Maximus (1)	SFO	7.06	0.994	2.55	8.47
			DFOP	5.8	0.9976	2.25	9.66
			HS	5.09	0.9981	2.33	9.89
			FOMC	4.75	0.9974	2.24	9.6
		Lettuce Maximus (2)	SFO	21.5	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

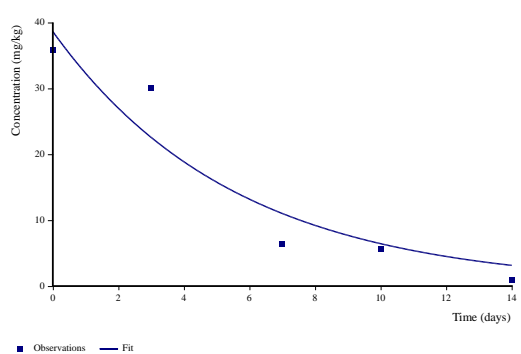
For all salad varieties in the greenhouse the X²-values for the best fit models were < 15% except for three species: Lettuce Maximus (2), Lettuce Fabietto (2) and Escarole Arlonia (1). However, the coefficients of determination (r²) were always > 0.91 and the visual fits for the chosen kinetics were good (see Figure).

R03AG12-01

Lettuce Maximus (1) (HS)

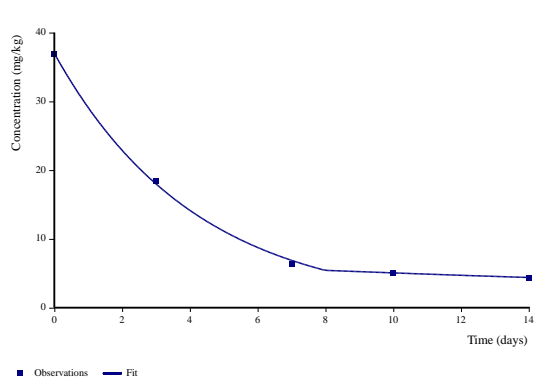


Lettuce Maximus (2) (SFO)

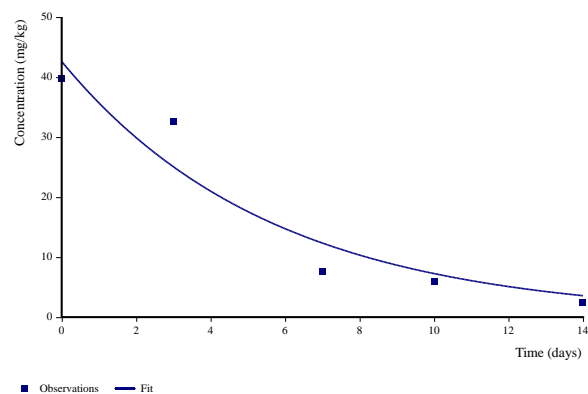


R03AG12-02

Lettuce Fabietto (1) (HS)



Lettuce Fabietto (2) (SFO)



R03AG12-03

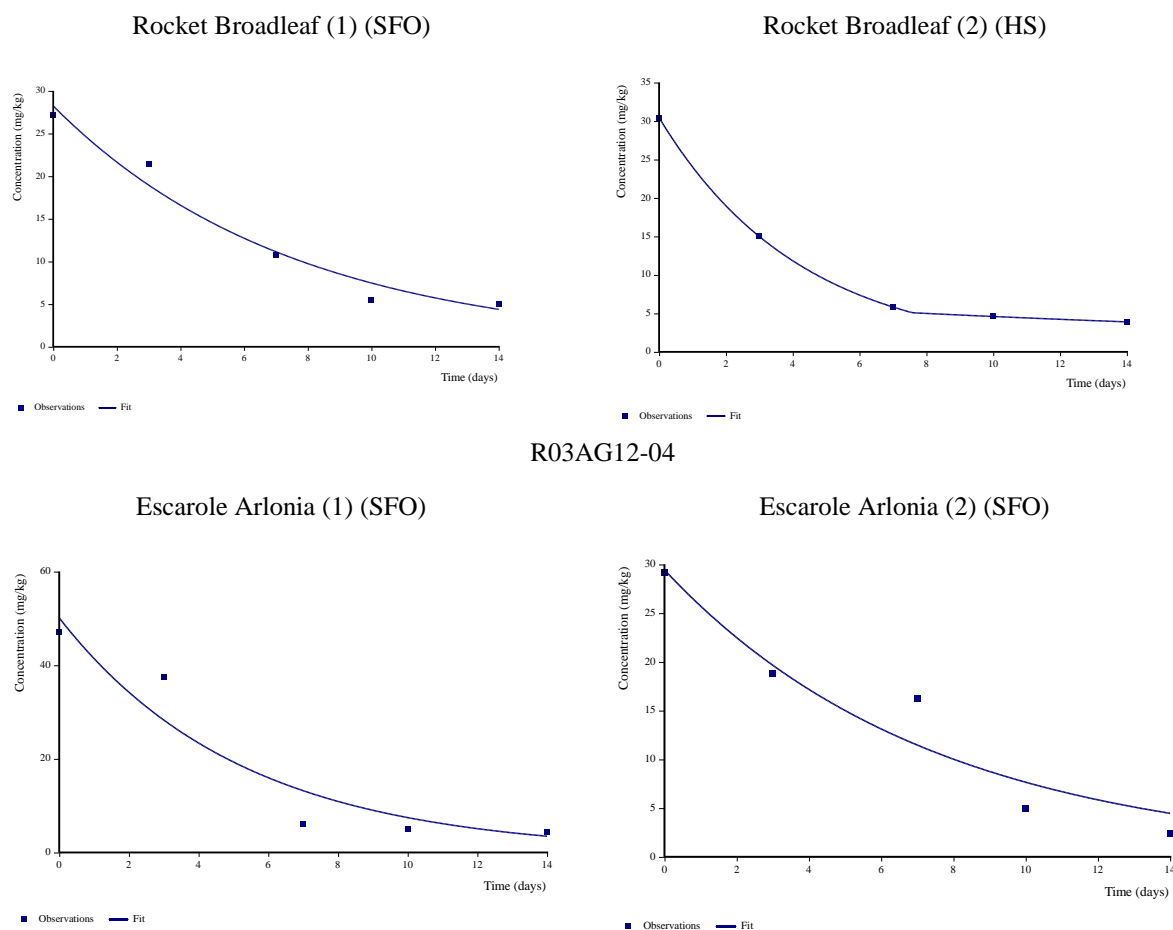


Figure A 10: Plot with the residue decline data of Zoxamide using the best fit kinetics for each salad variety - indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC

In the following tables the CAKE results are presented in more detail for all different kinetics; together with the DT₅₀ values, the values for statistical goodness of fit (X²) and the coefficients of determination (r²), 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 2-27: Results of CAKE calculations for all kinetic models (indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC) - R03AG12-01, Lettuce Maximus (1)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	2.55	2.25	2.33	2.24
DT₉₀ [days]	8.47	9.66	9.89	9.6
X² [%]	7.06	5.8	5.09	4.75
r²	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 CI (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 CI (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 2-28: Results of CAKE calculations for all kinetic models (indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC) - R03AG12-01, Lettuce Maximus (2)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	3.87	3.87	4.18	3.87
DT₉₀ [days]	12.9	12.9	10.9	12.9
X² [%]	21.5	30.6	29.3	24.5
r²	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 CI (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 CI (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 2-29: Results of CAKE calculations for all kinetic models (indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC) - R03AG12-02, Lettuce Fabietto (1)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	3.15	2.77	2.89	2.76
DT₉₀ [days]	10.5	14.1	18.8	12.3
X² [%]	8.22	6.08	2.23	6.77
r²	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 CI (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 CI (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 2-30: Results of CAKE calculations for all kinetic models (indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC) - R03AG12-02, Lettuce Fabietto (2)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	3.92	3.92	3.92	3.92
DT₉₀ [days]	13	13	13	13
X² [%]	19.3	27.6	27.6	22.1
r²	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 CI (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 CI (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 2-31: Results of CAKE calculations for all kinetic models (indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC) - R03AG12-03, Rocket salad Broadleaf (1)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	5.22	5.22	5.11	5.22
DT₉₀ [days]	17.3	17.3	70.9	17.3
X²-err [%]	8.94	12.8	12.5	10.2
r²	0.9692	0.9692	0.9708	0.9692
X² [%]	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
r²	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	k1 = 0.55 k2 = nd	α = nd β = nd

		g = nd $M_{(0)} = 68.67$	tb = nd $M_{(0)} = 68.37$	$M_{(0)} = 37.93$
t-test	p(k) = 0.00244	p(k1) = 0.07013 p(k2) = nd	p(k1) = 0.07508 p(k2) = nd	-

Table A 2-32: Results of CAKE calculations for all kinetic models (indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC) - R03AG12-03, Rocket salad Broadleaf (2)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	3.27	2.78	2.94	2.74
DT₉₀ [days]	10.9	>10,000	20	13.6
X² [%]	8.72	4.36	0.0648	5.67
r²	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 $M_{(0)} = 30.43$	$\alpha = 2.208$ $\beta = 7.424$ $M_{(0)} = 30.51$
Lower CI (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 $M_{(0)} = 30.24$	$\alpha = -3.195$ $\beta = -17.16$ $M_{(0)} = 25.47$
Upper CI (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 $M_{(0)} = 30.62$	$\alpha = 7.612$ $\beta = 32.01$ $M_{(0)} = 35.55$
t-test	p(k) = 0.00148	p(k1) = 0.1109 p(k2) = 0.5	p(k1) = 0.000375 p(k2) = 0.009845	-

Table A 2-33: Results of CAKE calculations for all kinetic models (indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC) - R03AG12-04, Escarole Arlonia (1)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	3.64	3.64	3.6	3.64
DT₉₀ [days]	12.1	12.1	12	12.1
X² [%]	22.1	31.5	31.4	25.2
r²	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 $M_{(0)} = 50.18$	$\alpha = 3380$ $\beta = 17700$ $M_{(0)} = 50.1$
Lower CI (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 $M_{(0)} = -97.03$	$\alpha = \text{nd}$ $\beta = \text{nd}$ $M_{(0)} = 14.83$
Upper CI (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 $M_{(0)} = 197.4$	$\alpha = \text{nd}$ $\beta = \text{nd}$ $M_{(0)} = 85.37$

t-test	p(k) = 0.01817	p(k1) = 0.132 p(k2) = nd	p(k1) = 0.136 p(k2) = 0.4998	-
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Table A 2-34: Results of CAKE calculations for all kinetic models (indoor, Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC) - R03AG12-04, Escarole Arlonia (2)

Model	SFO	DFOP	HS	FOMC
DT₅₀ [days]	5.15	5.15	5.15	5.15
DT₉₀ [days]	17.1	17.1	52.8	17.1
X² [%]	14.8	21.1	21.1	16.9
r²	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 CI (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 CI (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	-

Overall

The best kinetic model was identified using primarily the statistical goodness of fit Chi Square (X²). Furthermore, the coefficient of determination (r²) and the visual fit.

Table A 2-35: 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

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

* Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC

** Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC

As a result of the kinetic evaluation of these residues data, zoxamide on/in salad plants decreased quickly. DT₅₀ values from field decline studies were found in the range of 1.79 to 11.6 days with a geometric mean DT₅₀ value (n= 8) of 4.8 (± 3.2) days. Under glasshouse conditions, zoxamide degraded on/in plants with DT₅₀ values of 2.33 to 5.22 days and a geometric mean DT₅₀ value (n= 8) of 3.6 (± 1.1) days. The DT₅₀ 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 DT₅₀ 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.

(Klein J., Klein M. & Mendel-Kreusel R. 2020)

A 2.7 Study 7 – Residue degradation of zoxamide in mono- and dicotyledonae plants under northern European growing conditions

Substance specific DT₅₀ values for residues dissipation of zoxamide were taken into account for refined PEC SW calculations. These values were obtained for salad plants in supervised residue studies (for MRL evaluation) 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. 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) in the field under Northern and Southern European growing conditions, inclusive a kinetic evaluation of the degradation data. These studies are summarised in the following. All available dissipation data of zoxamide on/in plants were kinetically evaluated by Klein & Mendel-Kreusel (2020) in report no. GOW1120-1.

Comments of zRMS:	The study was evaluated and accepted in Section 7.
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Report	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 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S16-05375, GLP, Not published
Guideline(s):	SANCO/4145/2000 EFSA Guidance document on Risk Assessment for Birds and Mammals (2009) SANCO/3029/99 rev. 4 (2000) FOCUS (2014)
Deviations:	For all three trials the growth stage of wheat (BBCH) at application A2 was higher (>19) than requested in the study plan. The reason was a different growth development of the two crops (sugar beet and wheat). There was no impact on study.
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the residue decline of zoxamide on/in feed items of herbivorous birds and mammals under representative growing conditions in Northern Europe (Germany) in the field: In sugar beet leaves (as surrogate dicotyledonae, representative for the feed item group “non-grass herbs”) and in wheat green mass above soil (as surrogate monocotyledonae, representative for the feed item group “grass and cereals”). The residues and degradation kinetics of the active ingredient were investigated after two applications of Zoxium 240 SC (240 g/L zoxamide, SC) 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). The early application timing of zoxamide to both plant groups is representative for the more sensitive phase for wild birds and mammals.

The study consisted of three field trials, S16-05375-01 to -03 and one residue analysis trial, S16-05375-L1. The field parts were carried out in three fields located in near Stutensee (trial -01), Pforzheim (trial -02) and near Brackenheim (trial -03), in Baden Württemberg, Germany. The field sites of all trials covered an area of 300 m² sugar beet and 300 m² summer wheat.

Sugar beet plants were planted on 05 April 2017 in trial -01, on 25 April 2017 in trial -02 and on 22 April 2017 in trial -03. Wheat was sown on 05 May 2017 in trial -01, on 17 May 2017 in trial -02 and on 19 May 2017 in trial -03. Samples were taken before each application and up to 16 days after the last application. One sampling before the 1st application served as control.

For the two specimen types, the sampling schedule was as follows: In trial -01, first sampling before the 1st application (control), 0 to 1 hour before the 2nd application, 3, 24, 48 hours after the 2nd application, and 4, 6, 8 and finally 16 days after the 2nd application. In trial -02, first sampling before the 1st application (control), 0 to 1 hour before the 2nd application, 3, 24, 48 hours after the 2nd application, and 4, 6, 8 and finally 15 days after the 2nd application. In trial -03, first sampling before the 1st application (control), 1 hour before the 2nd application, 3, 24, 48 hours after the 2nd application, and 4, 6, 8 and finally 16 days after the 2nd application.

The samples were weighed in the field and frozen immediately on dry ice. Retained samples were taken for all matrices. All residues samples were stored in the freezer within 6 hours after collection in the field. The samples were stored and shipped frozen. The maximum freezer storage time of samples was 88 days for sugar beet leaves and 90 days for wheat green mass. At the testing facility and test site the samples were stored deep frozen at $\leq -18^{\circ}\text{C}$ for a maximum of 90 days until extraction and residue analysis. Residue analysis took place within 7 days after extraction.

The residues of the active ingredients on/in sugar beet leaves and wheat green mass were analysed with

fully validated analytical methods according to SANCO/3029/99 rev. 4. The method for the determination of zoxamide in sugar beet leaves and wheat green mass was validated in this study together with the analytical part of study under EAS study number S16-05376 and CIP Phase ID 17E10095-01-RAVE, according to SANCO Guideline 3029/99 rev. 4. Specimens were extracted (in analogy to the QuEChERS multi residue method) with acetonitrile/water, phase separation was done by addition of buffer salt mixture. The final analysis was conducted with highly specific HPLC with MS/MS detection. Recoveries in the fortified samples were within the acceptable range of 70 - 110 %, therefore the stability of the analyte during storage of the final sample extracts is sufficiently proven.

The degradation kinetics of the active substances were analysed according to the recommendations of the EFSA Guidance document on Risk Assessment for Birds and Mammals (2009) and the Guidance document on Estimating Persistence and Degradation Kinetics from Environmental Studies on Pesticides in EU Registration (FOCUS 2014). The calculation of the DT50 values and DT90 values as well as the fitting of the kinetic degradation models was done using the computer software KinGU II (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 operating system was Microsoft Windows 7 Professional.

Materials and methods

A. Materials

1. Test material	ZOXIUM 240 SC
Lot/batch:	SB 2401
Active substance content:	240 g/L zoxamide (nominal), 232 g/L zoxamide (analysed)
Expiry date:	April 2018

B. Methods

1. Experimental conditions

The study comprised three sugar beet and wheat fields, one per trial. All trials were treated with two applications of Zoxium 240 SC at a nominal rate of 180 g zoxamide/ha. The field sites were located near Stutensee (trial -01), Pforzheim (trial -02) and near Brackenheim (trial -03), in Baden Württemberg, Germany. The agricultural practices and sugar beet / wheat varieties were in accordance with the local farming practices.

Each trial was designed to produce a single sample for each food type at each sampling date (i.e. to provide an assessment of the average residue level as well as to ensure that sufficient material was collected for the actual residue analysis). To minimise edge effects from neighbouring fields, sampling was not carried out at the outer 50 cm of the plot.

During the study, weather data obtained from portable data loggers on the field sites and from weather stations in the vicinity of the field sites including precipitation and air temperature, were taken. During applications and samplings, the climatic conditions (GLP data) were measured at the field site with a portable thermo-hygrometer, a soil thermometer and a portable anemometer. Additional data for the long-term average were taken from official weather stations (non-GLP data).

No other formulations containing zoxamide were applied during the trial period onto the plots.

2. Sampling

Samples of different food items for birds and mammals were collected for residue analysis. Two categories of potential bird and mammalian food items were considered:

1. Sugar beet green mass / leaves
2. Wheat green mass / leaves

For each trial 9 samplings per category were carried out. The first sampling took place before the 1st application and was used as control sample.

For the two specimen types, the sampling schedule was as follows: In trial -01, first sampling before the 1st application (control), 0 to 1 hour before the 2nd application, 3, 24, 48 hours after the 2nd application, and 4, 6, 8 and finally 16 days after the 2nd application. In trial -02, first sampling before the 1st application (control), 0 to 1 hour before the 2nd application, 3, 24, 48 hours after the 2nd application, and 4, 6, 8 and finally 15 days after the 2nd application. In trial -03, first sampling before the 1st application (control), 1 hour before the 2nd application, 3, 24, 48 hours after the 2nd application, and 4, 6, 8 and finally 16 days after the 2nd application.

The samples were sampled randomly on 12 locations per trial. There was at least 50 g plant material taken per field at each sampling occasion. Samplings were done by hand or with scissors. Samples were taken with a minimum distance of 0.5 m to the border of the plot. Samples were taken with a minimum distance of 0.5 m to the border of the plot. The samples of all locations of one field were put together to one pooled sample.

The samples were weighed in the field and frozen immediately on dry ice. Retained samples were taken for all matrices. At the testing facility and test site the samples were stored deep frozen at $\leq -18^{\circ}\text{C}$ for a maximum of 90 days until extraction and residue analysis.

3. Description of the analytical procedure

The data presented in this report demonstrate that the used method permits the determination of residues of zoxamide in sugar beet leaves (representing the feed item group “non-grass herbs”) and in wheat plants (representing the feed item group “grass and cereals”) (without roots) with accuracy, precision and repeatability. The method was based on QuEChERS multi-residue method, validated by RICHTER (2014) according to SANCO/825/00 rev. 8.1 for the determination of zoxamide in various crop commodities. This method was validated under the laboratory conditions of CIP for the determination of residues of zoxamide in sugar beet leaves and wheat plants according to guideline SANCO/3029/99 rev. 4. For this purpose, recovery experiments were performed by fortifying control (untreated) specimens.

10 g (± 0.1 g) of sugar beet leaves and wheat plant specimens were weighed into 50 mL single use centrifuge tubes. Recovery samples were fortified at this step. 10 mL acetonitrile were added and the samples were homogenised for at least 2 min using a vortex mixer. Thereafter, QuEChERS EN15662 salt-mixture (1 g sodium citrate, 0.5 g sodium hydrogencitrate sesquihydrate, 4 g magnesium sulphate, 1 g sodium chloride) was added, thoroughly shaken and mixed again on a vortex mixer for at least 1 min. The samples were centrifuged at 4000 min⁻¹ for at least 5 minutes. An aliquot of 1 mL of the supernatant was transferred into a tube prepared with 25 mg PSA (primary-secondary amino phase) and 150 mg anhydrous magnesia sulphate and mixed on a Vortex mixer for 1 min. The extract was filtered through a single-use syringe filter (0.45 μm) into an autosampler vial (1.8 mL). 0.5 mL of this solution were transferred into a second vial, 5 μL of acetonitrile + 5 % formic acid were added, the vial capped and thoroughly shaken. 50 μL of this sample extract were then diluted with 950 μL acetonitrile/water (20:80, v/v) plus 0.1 % formic acid. If necessary, these final extracts were diluted further with final extract of untreated samples to achieve final concentrations falling within the calibrated concentration range of the detection system.

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

4. Calculation of initial concentration (C0) and DT50/DT90 values

The degradation time of zoxamide was calculated, including information about the kinetics of the decay according to the recommendations of the guidance document on estimating persistence and degradation kinetics from environmental studies on pesticides in EU registration (FOCUS 2014).

The calculation of the DT50 values and DT90 values as well as the fitting of the kinetic degradation models was done using the computer software KinGU II (version 2.2012). The fitting of the analysed data was calculated for four kinetic degradation models – single first order kinetic (simple first order), first order multi compartment kinetic (GUSTAFSON & HOLDEN, 1990), hockey stick kinetic (bi-phasic) and double first order kinetic (bi-exponential). The operating system was Microsoft Windows 7 Professional. The significance of the used models was determined, considering the significance of the parameters k, k1 and k2, which was part of the results obtained from the calculation with KinGU II.

For both commodities, the analysed residues after the last application (2nd application), i.e. starting from three hours after the last application to 16/15/16 days after the last application were chosen to establish degradation kinetics for the single trials. For the two commodities timings were calculated separately from the end of application until the samples were put on dry ice (i.e. time degradation of residues stops). Times were rounded to full hours.

Results and discussions

A. Weather conditions

The climatic conditions during trial -01 compared to the long-term average (1961-1990) revealed higher average temperatures for May and June 2017. During the trial period the rainfall recorded at the field site was 48.8 mm.

The climatic conditions during trial -02 compared to the long-term average (1981-2010) revealed higher average temperatures for June 2017. During the trial period the rainfall recorded at the field site was 14.8 mm.

The climatic conditions during trial -03 compared to the long-term average (1971-2000) revealed higher average temperatures for June 2017. During the trial period the rainfall recorded near the field site (~ 8.8 km) was 44.0 mm.

B. Zoxamide residues

In the control samples, taken directly before the 1st application, concentrations analysed were below the LOD (0.003 mg/kg) in all trials.

Zoxamide in/on sugar beet leaves

Zoxamide concentrations in sugar beet leaves of the three trials were 0.53 mg/kg (trial -01), 0.54 mg/kg (trial -02), and 0.74 mg/kg (trial -03) shortly before the 2nd application (0-1 HBA2). The highest concentrations were analysed three hours after the 2nd application in trial -01 and -02 and 24 hours after the 2nd application in trial -03 (trial -01: 6.84 mg/kg; trial -02: 7.60 mg/kg, trial -03: 6.70 mg/kg). At the last sampling 16/15/16DAA2 concentrations for the field trials were 0.22 mg/kg (trial -01), 0.66 mg/kg (trial -02) and 0.16 mg/kg (trial -03). A summary of the residue levels found in sugar beet leaf samples is shown in the following table.

Table A 2-36: Zoxamide residue levels determined in/on sugar beet leaves (individual values of all field sites) after 2 applications of Zoxium 240 SC

Timing (trial -01/-02/-03)	Trial		
	-01	-02	-03
	[mg/kg]	[mg/kg]	[mg/kg]
0/1/0DBA1	<LOD	<LOD	<LOD

0/0/1HBA2	0.53	0.54	0.74
3/3/3HAA2	6.84	7.60	5.44
24/24/24HAA2	5.30	3.96	6.70
48/48/48HAA2	2.00	3.08	5.50
4/4/4DAA2	1.90	1.58	2.44
6/6/6DAA2	1.76	1.77	1.27
8/8/8DAA2	0.71	0.83	0.62
16/15/16DAA2	0.22	0.66	0.16

DBA: days before application, DAA: days after application,
HAA: hours after application, HBA: hours before application,
LOD: level of detection (0.003 mg/kg)

In trial -01 none of the models achieved the critical values < 15 for χ^2 -error. In trial -02 the calculation of degradation rates for zoxamide in sugar beet leaves achieved critical values < 15 for χ^2 -error for the FOMC and DFOP model. In trial -03 the calculation of degradation rates for zoxamide in sugar beet leaves achieved critical values < 15 for χ^2 -error for the HS model. The determination coefficient of $r^2 > 0.85$ was achieved for all trials for all models. In trial -01 the FOMC and DFOP models showed the highest r^2 with 0.94. However, the DFOP model was not significant at $p(k) < 0.05$. In trial -02 the FOMC and DFOP models also achieved the highest r^2 with 0.99. Here, too, the DFOP model was not significant at $p(k) < 0.05$. Therefore, for both trials (-01 and -02) the SFO model was used for calculation of degradation rates of zoxamide in sugar beet leaves. In trial -03 the HS model reached the highest r^2 with 0.98 and one of the two constants was significant at $p(k) < 0.05$. The results of the calculation showed DT50 values between 1.81 and 3.55 days and DT90 values between 6.02 and 7.79 days, respectively for the degradation of zoxamide in sugar beet leaves. The calculated χ^2 -errors for the three trials were 20.35 (SFO), 19.55 (SFO) and 10.34 (HS) for trials -01, -02 and -03, respectively. The calculated r^2 for the three trials were 0.92 (SFO), 0.93 (SFO) and 0.98 (HS) for trials -01, -02 and -03, respectively.

Zoxamide in/on wheat green mass

Zoxamide concentrations in wheat green mass were 1.80 mg/kg (trial -01), 1.88 mg/kg (trial -02) and 1.25 mg/kg (trial -03) shortly before 2nd application (0-1 HBA2). The highest concentrations were analysed three hours after the 2nd application in trial -01, -02 and -03 (trial -01: 10.1 mg/kg, trial -02: 9.17 mg/kg, trial -03: 9.74 mg/kg). At the last sampling 16/15/16DAA2 concentrations for the field trials were 0.27 mg/kg (trial -01), 0.72 mg/kg (trial -02) and 0.28 mg/kg (trial -03). A summary of the residue levels found in wheat green mass samples is shown in the following table.

Table A 2-37: Zoxamide residue levels determined in/on wheat green mass (individual values of all field sites) after 2 applications of Zoxium 240 SC

Timing (trial -01/-02/-03)	Trial		
	-01	-02	-03
	[mg/kg]	[mg/kg]	[mg/kg]
0/1/0DBA1	<LOD	<LOD	<LOD
0/0/1HBA2	1.80	1.88	1.25
3/3/3HAA2	10.1	9.17	9.74
24/24/24HAA2	8.26	7.70	6.77
48/48/48HAA2	4.60	8.24	6.30
4/4/4DAA2	3.55	5.91	4.71
6/6/6DAA2	2.26	3.02	3.30
8/8/8DAA2	2.64	2.22	1.86
16/15/16DAA2	0.27	0.72	0.28

DBA: days before application, DAA: days after application,
HAA: hours after application, HBA: hours before application,

LOD: level of detection (0.003 mg/kg)

In trials -01, -02 and -03 the calculation of degradation rates for zoxamide in wheat green mass achieved critical values < 15 for χ^2 -error for all models, with one exception. In trial -01 the χ^2 -error was > 15 for the HS model. All models showed a determination coefficient of $r^2 > 0.85$. As the t-test of the SFO model for all trials was significant ($p(k) < 0.05$) the SFO model was used to calculate the degradation rates of the trials. The results of the calculation showed DT50 values between 2.74 and 4.31 days and DT90 values between 9.10 and 14.32 days, respectively for the degradation of zoxamide in wheat green mass. The calculated χ^2 -errors for the three trials were 13.65 (SFO), 10.22 (SFO) and 8.04 (SFO) for trials -01, -02 and -03, respectively. The calculated r^2 for the three trials were 0.95 (SFO), 0.95 (SFO) and 0.97 (SFO) for trials -01, -02 and -03, respectively.

C. Calculation of initial concentration (C0) DT50/DT90 values

Sugar Beet Leaves

In trial -01 none of the models achieved the critical values < 15 for χ^2 -error. In trial -02 the calculation of degradation rates for zoxamide in sugar beet leaves achieved critical values < 15 for χ^2 -error for the FOMC and DFOP model. In trial -03 the calculation of degradation rates for zoxamide in sugar beet leaves achieved critical values < 15 for χ^2 -error for the HS model. The determination coefficient of $r^2 > 0.85$ was achieved for all trials for all models. In trial -01 the FOMC and DFOP models showed the highest r^2 with 0.94. However, the DFOP model was not significant at $p(k) < 0.05$. In trial -02 the FOMC and DFOP models also achieved the highest r^2 with 0.99. Here, too, the DFOP model was not significant at $p(k) < 0.05$. Therefore, for both trials (-01 and -02) the SFO model was used for calculation of degradation rates of zoxamide in sugar beet leaves. In trial -03 the HS model reached the highest r^2 with 0.98 and one of the two constants was significant at $p(k) < 0.05$. The results of the calculation showed DT50 values between 1.81 and 3.55 days and DT90 values between 6.02 and 7.79 days, respectively for the degradation of zoxamide in sugar beet leaves. The calculated χ^2 -errors for the three trials were 20.35 (SFO), 19.55 (SFO) and 10.34 (HS) for trials -01, -02 and -03, respectively. The calculated r^2 for the three trials were 0.92 (SFO), 0.93 (SFO) and 0.98 (HS) for trials -01, -02 and -03, respectively.

Table A 2-38: Results and parameters of the kinetic degradation of zoxamide in/on sugar beet leaves (Trial S16-05375-01)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	1.94	1.43	1.37	2.05
DT ₉₀ [days]	6.45	8.91	9.86	6.56
CHI ² -err [%]	20.35	18.02	19.01	24.22
r ²	0.92	0.94	0.94	0.92
parameter	k = 0.35709	α = 1.4887	k1 = 0.80186	k1 = 0.002558
	M(0) = 6.95022	β = 2.4099	k2 = 0.11990	k2 = 0.357086
		M(0) = 7.5557	g = 0.67453	tb = 0.112641
			M(0) = 7.58528	M(0) = 6.678141
lower CI	k = 0.16253	α = -0.8153	k1 = -0.29060	k1 = -3.931317
	M(0) = 5.33129	β = -3.5004	k2 = -0.17975	k2 = 0.102682
		M(0) = 5.5901	g = -0.04745	tb = -0.461000
			M(0) = 5.73028	M(0) = 2.656454
upper CI	k = 0.552	α = 3.793	k1 = 1.894	k1 = 3.936
	M(0) = 8.569	β = 8.320	k2 = 0.420	k2 = 0.611
		M(0) = 9.521	g = 1.397	tb = 0.686
			M(0) = 9.440	M(0) = 10.700
t-test	p(k): 0.007794	-	p(k1): 0.12292	p(k1): 0.4995
			p(k2): 0.24506	p(k2): 0.0353

SFO = Single first order kinetic;
FOMC = First order multi compartment kinetic;
DFOP = Double first order kinetic;
HS = Hockey stick kinetic
M(0) = initial concentration
CI = confidence interval
t = time after time of initial concentration
k = rate constant (ln(2)/DT50)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
N = DT90/DT50-3.32
DT₅₀ = estimated from the data
DT₉₀ = estimated from the data
k₁ = rate constant for the fast degradation phase (ln(2)/DT50f)
k₂ = rate constant for the slow degradation phase (ln(2)/DT50s)
tb = break point time estimated from the data rate
g = 1-F
F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Table A 2-39: Results and parameters of the kinetic degradation of zoxamide in/on sugar beet leaves (Trial S16-05375-02)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	1.81	0.86	0.93	1.82
DT ₉₀ [days]	6.02	10.99	10.17	6.02
CHI ² -err [%]	19.55	7.27	8.62	23.27
r ²	0.93	0.99	0.99	0.93
parameter	k = 0.3825	$\alpha = 0.77533$	k ₁ = 1.40435	k ₁ = 0.004787
	M(0) = 7.2441	$\beta = 0.59437$	k ₂ = 0.12918	k ₂ = 0.382458
		M(0) = 8.84162	g = 0.62789	tb = 0.003585
			M(0) = 8.52512	M(0) = 7.234198
lower CI	k = 0.1650	$\alpha = 0.43121$	k ₁ = -0.18605	k ₁ = -4.077415
	M(0) = 5.6238	$\beta = -0.04523$	k ₂ = -0.02383	k ₂ = 0.058166
		M(0) = 7.54307	g = 0.033830	tb = -3.011862
			M(0) = 7.04669	M(0) = -3.057741
upper CI	k = 0.600	$\alpha = 1.119$	k ₁ = 2.995	k ₁ = 4.087
	M(0) = 8.864	$\beta = 1.234$	k ₂ = 0.282	k ₂ = 0.707
		M(0) = 10.140	g = 0.917	tb = 3.019
			M(0) = 10.004	M(0) = 17.526
t-test	p(k): 0.009152	-	p(k ₁): 0.090971	p(k ₁): 0.4992
			p(k ₂): 0.098278	p(k ₂): 0.0519

SFO = Single first order kinetic;
FOMC = First order multi compartment kinetic;
DFOP = Double first order kinetic;
HS = Hockey stick kinetic
M(0) = initial concentration
CI = confidence interval
t = time after time of initial concentration
k = rate constant (ln(2)/DT50)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
N = DT90/DT50-3.32
DT₅₀ = estimated from the data
DT₉₀ = estimated from the data
k₁ = rate constant for the fast degradation phase (ln(2)/DT50f)
k₂ = rate constant for the slow degradation phase (ln(2)/DT50s)
tb = break point time estimated from the data rate
g = 1-F
F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Table A 2-40: Results and parameters of the kinetic degradation of zoxamide in/on sugar beet leaves (Trial S16-05375-03)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	3.09	3.65	3.09	3.55
DT ₉₀ [days]	10.25	12.14	10.25	7.79
CHI ² -err [%]	21.02	23.75	25.02	10.34
r ²	0.89	0.89	0.89	0.98
parameter	k = 0.22460	$\alpha = 1.365e^{+03}$	k1 = 0.224604	k1 = 1.704e ⁻⁰⁸
	M(0) = 6.92205	$\beta = 7.187e^{+03}$	k2 = 0.085447	k2 = 3.798e ⁻⁰¹
		M(0) = 6.588	g = 1.000000	tb = 1.725
			M(0) = 6.922004	M(0) = 6.070
lower CI	k = 0.12070	$\alpha = -1.448e^{+04}$	k1 = -0.052762	k1 = -2.884e ⁻⁰¹
	M(0) = 5.41794	$\beta = -7.627e^{+04}$	k2 = -0.007701	k2 = 2.306e ⁻⁰¹
		M(0) = 5.051	g = -0.218086	tb = 6.145e ⁻⁰¹
			M(0) = 4.102791	M(0) = 4.901
upper CI	k = 0.329	$\alpha = 17211.434$	k1 = 0.502	k1 = 0.288
	M(0) = 8.426	$\beta = 90641.070$	k2 = 0.179	k2 = 0.529
		M(0) = 8.125	g = 2.218	tb = 2.835
			M(0) = 9.741	M(0) = 7.239
t-test	p(k): 0.00410	-	p(k1): 0.10534	p(k1): 0.50000
			p(k2): 0.08502	p(k2): 0.00775

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
 N = DT90/DT50-3.32
 DT50 = estimated from the data
 DT90 = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)
 k2 = rate constant for the slow degradation phase (ln(2)/DT50s)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Wheat Green Mass

In trials -01, -02 and -03 the calculation of degradation rates for zoxamide in wheat green mass achieved critical values < 15 for χ^2 -error for all models, with one exception. In trial -01 the χ^2 -error was > 15 for the HS model. All models showed a determination coefficient of $r^2 > 0.85$. As the t-test of the SFO model for all trials was significant ($p(k) < 0.05$) the SFO model was used to calculate the degradation rates of the trials. The results of the calculation showed DT50 values between 2.74 and 4.31 days and DT90 values between 9.10 and 14.32 days, respectively for the degradation of zoxamide in wheat green mass. The calculated χ^2 -errors for the three trials were 13.65 (SFO), 10.22 (SFO) and 8.04 (SFO) for trials -01, -02 and -03, respectively. The calculated r^2 for the three trials were 0.95 (SFO), 0.95 (SFO) and 0.97 (SFO) for trials -01, -02 and -03, respectively.

Table A 2-41: Results and parameters of the kinetic degradation of zoxamide in/on wheat green mass (Trial S16-05375-01)

Model	SFO	FOMC	DFOP	HS
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DT₅₀ [days]	2.74	2.07	1.97	2.74
DT₉₀ [days]	9.10	12.59	12.64	9.10
CHI²-err [%]	13.65	11.42	11.85	16.24
r²	0.95	0.97	0.97	0.95
parameter	k = 0.25314	α = 1.5420	k1 = 0.68299	k1 = 0.25314
	M(0) = 10.04582	β = 3.6464	k2 = 0.11975	k2 = 0.13547
		M(0) = 10.8462	g = 0.54619	tb = 19.77503
			M(0) = 10.92615	M(0) = 10.04581
lower CI	k = 0.16501	α = -0.2238	k1 = -0.13113	k1 = 0.12963
	M(0) = 8.62295	β = -2.7295	k2 = -0.04693	k2 = 0.02685
		M(0) = 8.6787	g = -0.03999	tb = -8.86985
			M(0) = 8.94225	M(0) = 7.91918
upper CI	k = 0.341	α = 3.308	k1 = 1.497	k1 = 0.377
	M(0) = 11.469	β = 10.022	k2 = 0.286	k2 = 0.244
		M(0) = 13.014	g = 1.132	tb = 48.420
			M(0) = 12.910	M(0) = 12.172
t-test	p(k): 0.00123	-	p(k1): 0.09933	p(k1): 0.01385
			p(k2): 0.12691	p(k2): 0.04607

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 α = $3.4735 \cdot N^{-0.8629}$
 β = $DT50 / (2^{(1/\alpha)} - 1)$
 N = $DT90 / DT50 - 3.32$
 DT50 = estimated from the data
 DT90 = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)
 k2 = rate constant for the slow degradation phase (ln(2)/DT50s)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Table A 2-42: Results and parameters of the kinetic degradation of zoxamide in/on wheat green mass (Trial S16-05375-02)

Model	SFO	FOMC	DFOP	HS
DT₅₀ [days]	4.31	4.29	4.31	4.31
DT₉₀ [days]	14.32	14.28	14.32	14.32
CHI²-err [%]	10.22	11.05	12.16	12.16
r²	0.95	0.95	0.95	0.95
parameter	k = 0.16082	α = $5.809e^{+02}$	k1 = 0.16082	k1 = 0.16082
	M(0) = 9.73916	β = $3.595e^{+03}$	k2 = 0.09269	k2 = 0.09655
		M(0) = 9.747	g = 1.00000	tb = 15.87861
			M(0) = 9.73915	M(0) = 9.73915
lower CI	k = 0.11922	α = $-5.805e^{+03}$	k1 = 0.08106	k1 = 0.11136
	M(0) = 8.60284	β = $-3.600e^{+04}$	k2 = -0.43351	k2 = 0.03006
		M(0) = 8.634	g = 0.51005	tb = -5.71376
			M(0) = 8.15279	M(0) = 8.21811
upper CI	k = 0.202	α = 6966.81	k1 = 0.241	k1 = 0.210
	M(0) = 10.875	β = 43187.14	k2 = 0.619	k2 = 0.163

		M(0) = 10.86	g = 1.490	tb = 37.471
			M(0) = 11.326	M(0) = 11.260
t-test	p(k): 0.000318	-	p(k1): 0.014455	p(k1): 0.003912
			p(k2): 0.376352	p(k2): 0.032665

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
 N = DT90/DT50-3.32
 DT50 = estimated from the data
 DT90 = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)
 k2 = rate constant for the slow degradation phase (ln(2)/DT50s)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

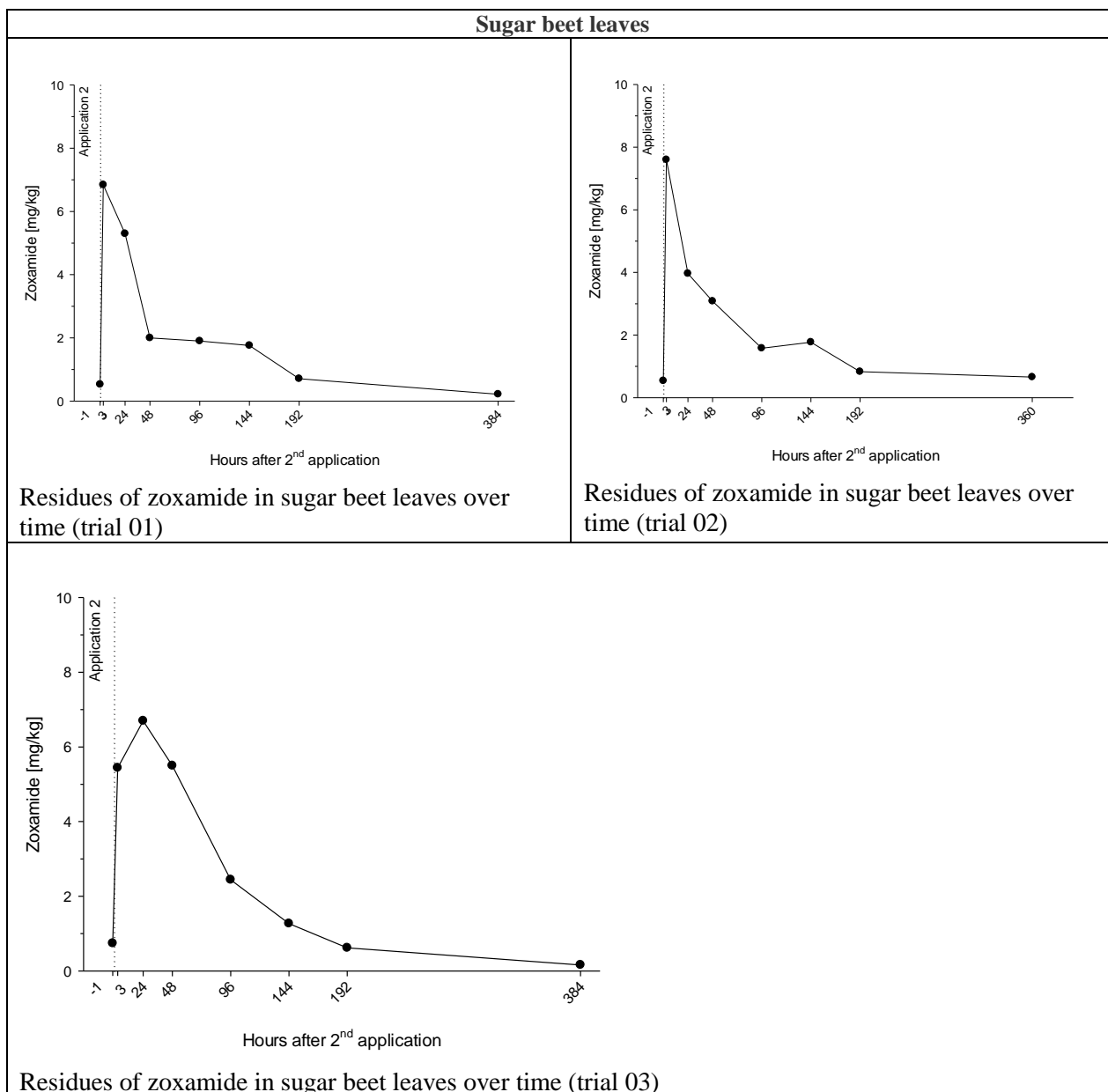
Table A 2-43: Results and parameters of the kinetic degradation of zoxamide in/on wheat green mass (Trial S16-05375-03)

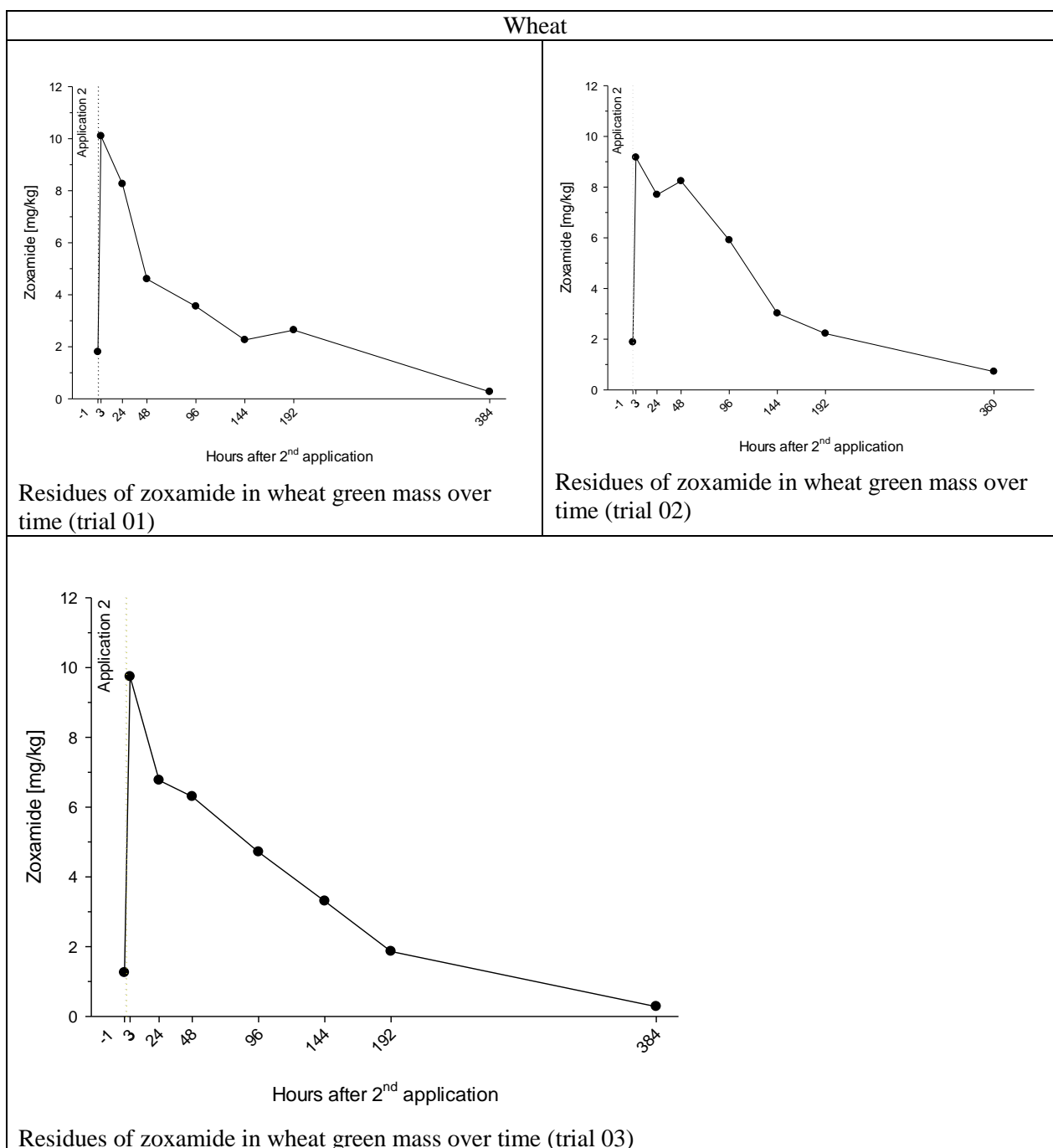
Model	SFO	FOMC	DFOP	HS
DT₅₀ [days]	3.65	3.57	3.65	3.80
DT₉₀ [days]	12.12	12.46	12.12	10.82
CHI²-err [%]	8.04	8.67	9.57	9.30
r²	0.97	0.97	0.97	0.98
parameter	k = 0.18999	$\alpha = 17.0640$	k1 = 1.431e ⁻⁰²	k1 = 0.182387
	M(0) = 9.33027	$\beta = 86.2323$	k2 = 1.900e ⁻⁰¹	k2 = 0.250785
		M(0) = 9.3832	g = 1.088e ⁻⁰⁷	tb = 6.000000
			M(0) = 9.330	M(0) = 9.253163
lower CI	k = 0.15018	$\alpha = -251.5509$	k1 = -1.573e ⁺⁰¹	k1 = 0.122714
	M(0) = 8.52435	$\beta = -1327.5442$	k2 = -7.374e ⁻⁰¹	k2 = -0.008406
		M(0) = 8.0851	g = -1.914	tb = -3.942312
			M(0) = 4.747	M(0) = 8.143282
upper CI	k = 0.23	$\alpha = 285.68$	k1 = 15.759	k1 = 0.242
	M(0) = 10.14	$\beta = 1500.01$	k2 = 1.117	k2 = 0.510
		M(0) = 10.68	g = 1.914	tb = 15.942
			M(0) = 13.913	M(0) = 10.363
t-test	p(k): 0.000118	-	p(k1): 0.4993	p(k1): 0.004657
			p(k2): 0.3575	p(k2): 0.077089

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
 N = DT90/DT50-3.32
 DT50 = estimated from the data
 DT90 = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)

k2 = rate constant for the slow degradation phase ($\ln(2)/DT50s$)
tb = break point time estimated from the data rate
g = 1-F
F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

The following figures show residues of zoxamide.





Conclusion

The residue decline of zoxamide on sugar beet leaves (as surrogate dicotyledonae plant) and wheat green mass (as surrogate monocotyledonae plant) has been studied in the field under representative growing conditions for Northern Europe (Germany). The degradation kinetics of the active ingredient were investigated after two applications of Zoxium 240 SC (240 g/L zoxamide, SC) 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).

The study was conducted in accordance to current guidelines.

For the degradation of zoxamide in sugar beet leaves, the single first order (SFO) degradation model was used for two trials (trials -01 and -02) – as recommended in Appendix H of the Birds and Mammals Guidance Document (2009) - and the hockey stick (HS) model was used for trial -03. DT₅₀ values were

calculated between 1.81 and 3.55 days and DT₉₀ values were calculated between 6.02 and 7.79 days.

For the degradation of zoxamide in wheat green mass, the single first order (SFO) degradation model was used in all of the three trials – as recommended in Appendix H of the Birds and Mammals Guidance Document (2009). DT₅₀ values were calculated between 2.74 and 4.31 days and DT₉₀ values were calculated between 9.10 and 14.32 days.

(Appeltauer A. 2020)

A 2.8 Study 8 - Residue degradation of zoxamide in mono- and dicotyledonae plants under northern European growing conditions

Comments of zRMS:	The study was evaluated and accepted in Section 7.
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Reference:	KCP 9.2.5/03
Report	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 the Netherlands in 2019 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S19-01450, GLP, Not published
Guideline(s):	SANCO/4145/2000 EFSA Guidance on Risk Assessment for Birds and Mammals (2009) SANCO/3029/99 rev. 4 SANCO/825/00 rev. 8.1 EFSA Technical Report (2019): Outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. FOCUS (2014)
Deviations:	No daily precipitation GLP data available. Reason for this deviation was a mistake during study conduct. Amount of rain in rain gauge was only recorded at every visit (not daily). Only non-GLP rain data are available for the report.
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the residue decline of zoxamide on/in feed items of herbivorous birds and mammals under representative growing conditions in The Netherlands in the field: In sugar beet leaves (as surrogate dicotyledonae, representative for the feed item group “non-grass herbs”) and in wheat green mass above soil (as surrogate monocotyledonae, representative for the feed item group “grass and cereals”). The residues and degradation kinetics of the active ingredient were investigated after two applications of Zoxium 240 SC (240 g/L zoxamide, SC) at application rates for zoxamide of 180 g a.i./ha with an interval of 7 days (BBCH 18-21 for sugar beet and wheat). The early application timing of zoxamide to both plant groups is representative for the more sensitive phase for wild birds and mammals.

The study consisted of one field trial, S19-01450-01 and one residue analysis trial, S19-01450-L1. The field part was carried out on a field located near PK Elst, Gelderland, The Netherlands. The field site of the trial covered an area of 675 m² sugar beet and 675 m² summer wheat.

Sugar beet plants were planted on 06 April 2019; wheat was sown on 03 May 2019. Samples were taken

before first application and up to 21 days after the second application. One sampling before the 1st application served as control.

For the two specimen types, the sampling schedule was as follows: the first sampling before the 1st application (control), 3, 24, 48 hours after the 2nd application, and 4, 5, 7, 14 and finally 21 days after the 2nd application. The samples were weighed in the field and frozen immediately on dry ice. Retained samples were taken for all matrices. All residues samples were stored in the freezer within 1 hour after collection in the field. The samples were stored and shipped frozen. The maximum storage time of samples was 28 days for sugar beet leaves and wheat green mass. The stability of the analyte during storage of the final sample extracts is sufficiently proven. The maximum freezer storage time of samples was 28 days for sugar beet leaves and wheat green mass. Residue analysis took place within 5 days after extraction.

The residues of the active ingredients on/in sugar beet leaves and wheat green mass were analysed with fully validated analytical methods according to SANCO/3029/99 rev. 4. The method for the determination of zoxamide in sugar beet leaves and wheat green mass has been previously validated according to guideline SANCO/3029/99 rev. 4 in a former study (Witte, A.; CIP Phase ID 17E10095-01-RAVE, analytical part of EAS study S16-05375) at an LOQ of 0.01 mg/kg for the matrices under investigation. It takes into account additional requirements of SANCO/825/00 rev. 8.1 and EFSA Technical Report (2019): Outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. Specimens were extracted (in analogy to the QuEChERS multi residue method) with acetonitrile/water, phase separation was done by addition of buffer salt mixture. The final analysis was conducted with highly specific HPLC with MS/MS detection. Recoveries in the fortified samples were within the acceptable range of 70 - 110 %, therefore the stability of the analyte during storage of the final sample extracts is sufficiently proven.

The degradation kinetics of the active ingredient was analysed according to the recommendations of the EFSA Guidance document on Risk Assessment for Birds and Mammals (2009) and the Guidance document on Estimating Persistence and Degradation Kinetics from Environmental Studies on Pesticides in EU Registration (FOCUS 2014). The calculation of the DT50 values and DT90 values as well as the fitting of the kinetic degradation models was done using the computer software KinGU II (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 operating system was Microsoft Windows 10 Professional.

Materials and methods

A. Materials

1. Test material	ZOXIUM 240 SC
Lot/batch:	SB 2401
Active substance content:	240 g/ zoxamide (nominal), 232 g/L zoxamide (analysed)
Expiry date:	February 2020

B. Methods

1. Experimental conditions

The study comprised one sugar beet and wheat field, trial S19-01450-01. The trial was treated with two applications of Zoxium 240 SC at a nominal rate of 180 g zoxamide/ha. The field site was located near PK Elst, Gelderland, in The Netherlands. The agricultural practices and sugar beet / wheat varieties were in accordance with the local farming practice.

The trial was designed to produce a single sample for each food type at each sampling date (i.e. to provide an assessment of the average residue level as well as to ensure that sufficient material was collected for the actual residue analysis).

During the study, weather data obtained from weather station in the vicinity of the field site including precipitation and air temperature was taken. During applications and samplings, the climatic conditions (GLP data) were measured at the field site with a portable thermo-hygrometer, a soil thermometer and a portable anemometer.

No other formulations containing zoxamide were applied during the trial period onto the plot.

2. Sampling

Samples of different food items for birds and mammals were collected for residue analysis. Two categories of potential bird and mammalian food items were considered:

1. Sugar beet leaves
2. Wheat

For each trial 9 samplings per category were carried out. The first sampling took place before the 1st application and was used as control sample.

For the two specimen types, the sampling schedule was as follows: the first sampling before the 1st application (control), 3, 24, 48 hours after the 2nd application, and 4, 5, 7, 14 and finally 21 days after the 2nd application. The samples were weighed in the field and frozen immediately on dry ice. Retained samples were taken for all matrices. All residues samples were stored in the freezer within 1 hour after collection in the field. The samples were stored and shipped frozen. The maximum storage time of samples was 28 days for sugar beet leaves and wheat green mass. The stability of the analyte during storage of the final sample extracts is sufficiently proven. The maximum freezer storage time of samples was 28 days for sugar beet leaves and wheat green mass. Residue analysis took place within 5 days after extraction.

The samples were taken randomly on at least 12 locations per sample. There were at least 500 g plant material taken at each sampling occasion. Samplings were done by hand or with a knife. Samples were taken with a minimum distance of 0.5 m to the border of the plot. The samples of all locations of one field were put together to one pooled sample per sampling occasion.

The samples were weighed in the field and frozen immediately on dry ice. Retained samples were taken for all matrices. All residues samples were stored in the freezer within 1 hour after collection in the field. The samples were stored and shipped frozen. The maximum storage time of samples was 28 days for sugar beet leaves and wheat green mass.

The samples were weighed in the field and frozen immediately on dry ice. Retained samples were taken for all matrices. All residues samples were stored in the freezer within 1 hour after collection in the field. The samples were stored and shipped frozen. The maximum storage time of samples was 28 days for sugar beet leaves and wheat green mass.

3. Description of the analytical procedure

The data presented in this report demonstrate that the used method permits the determination of residues of zoxamide in in sugar beet leaves (representing the feed item group “non-grass herbs”) and in wheat plants without roots (representing the feed item group “grass and cereals”) with accuracy, precision and repeatability. The method is based on QuEChERS multi-residue method, validated by RICHTER (2014) according to SANCO/825/00 rev. 8.1 for the determination of zoxamide in various crop commodities. This method was validated under the laboratory conditions of CIP for the determination of residues of

zoxamide in sugar beet leaves and wheat green mass according to guideline SANCO/3029/99 rev. 4. For this purpose, recovery experiments were performed by fortifying control (untreated) specimens.

10 g (\pm 0.1 g) of sugar beet leaves and wheat green mass specimens were weighed into 50 mL single-use centrifuge tubes. Recovery samples were fortified at this step. 10 mL acetonitrile were added and the samples were homogenised for at least 2 min using a vortex mixer. Thereafter, QuEChERS EN15662 salt-mixture (1 g sodium citrate, 0.5 g sodium hydrogencitrate sequehydrate, 4 g magnesium sulphate, 1 g sodium chloride) was added, thoroughly shaken and mixed again on a vortex mixer for at least 1 min. The samples were centrifuged at 4000 min⁻¹ for at least 5 minutes. An aliquot of 1 mL of the supernatant was transferred into a tube prepared with 25 mg PSA (primary-secondary amino phase) and 150 mg anhydrous magnesium sulphate and mixed on a Vortex mixer for 1 min. The extract was filtered through a single-use syringe filter (0.45 μ m) into an autosampler vial (1.8 mL). 0.5 mL of this solution were transferred into a second vial, 5 μ L of acetonitrile + 5 % formic acid were added, the vial capped and thoroughly shaken. 50 μ L of this sample extract were then diluted with 950 μ L acetonitrile/water (20:80, v/v) plus 0.1 % formic acid. If necessary, these final extracts were diluted further with final extract of untreated samples to achieve final concentrations falling within the calibrated concentration range of the detection system.

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

4. Calculation of initial concentration (C₀) and DT₅₀/DT₉₀ values

The degradation time of zoxamide was calculated, including information about the kinetics of the decay according to the recommendations of the guidance document on estimating persistence and degradation kinetics from environmental studies on pesticides in EU registration (FOCUS 2014).

The calculation of the DT₅₀ values and DT₉₀ values as well as the fitting of the kinetic degradation models was done using the computer software KinGU II (version 2.2012). The fitting of the analysed data was calculated for four kinetic degradation models – single first order kinetic (simple first order), first order multi compartment kinetic (GUSTAFSON & HOLDEN, 1990), hockey stick kinetic (bi-phasic) and double first order kinetic (bi-exponential). The operating system was Microsoft Windows 7 Professional. The significance of the used models was determined, considering the significance of the parameters k, k₁ and k₂, which was part of the results obtained from the calculation with KinGU II.

For both commodities, the analysed residues after the last application (2nd application), i.e. starting from three hours after the last application to 21 days after the last application were chosen to establish degradation kinetics. For the two commodities timings were calculated separately from the end of application until the samples were put on dry ice (i.e. time degradation of residues stops). Times were rounded to full days (two digits).

Results and discussions

A. Weather conditions

During the trial period the daily average temperatures were between 13.7 °C and 28.2 °C. The rainfall recorded at the field site was 38 mm during the period from first sampling before application to last sampling.

B. Zoxamide residues

In the control samples of sugar beet leaves and wheat green mass, taken one day before the 1st application, concentrations analysed were below the LOD (0.003 mg/kg).

Zoxamide in/on sugar beet leaves

Zoxamide concentrations in sugar beet leaves were highest at the first sampling after the second application (3HAA2) with 7.09 mg/kg. Subsequently residues decreased to 1.68 mg/kg at the last sampling (21DAA2).

A summary of the residue levels found in sugar beet leaf samples is shown in the following table.

Table A 2-44: Zoxamide residues in/on sugar beet leaves

Timing	Trial
	S19-01450-01
	[mg/kg]
1DBA1	<LOD
3HAA2	7.09
24HAA2	7.07
48HAA2	6.16
4DAA2	5.68
5DAA2	4.83
7DAA2	4.23
14DAA2	3.51
21DAA2	1.68

DBA: days before application, DAA: days after application,
HAA: hours after application, HBA: hours before application,
LOD: level of detection (0.003 mg/kg)

Zoxamide in/on wheat green mass

Zoxamide concentrations in wheat samples were at 6.95 mg/kg at the first sampling after the second application (3HAA2). On the following sampling (24HAA2) the highest residue was observed with 7.43 mg/kg. Subsequently residues decreased to 0.85 mg/kg at the last sampling (21DAA2). A summary of the residue levels found in wheat green mass samples is shown in the following table.

Table A 2-45: Zoxamide residues in/on wheat green mass

Timing	Trial
	S19-01450-01
	[mg/kg]
1DBA1	<LOD
3HAA2	6.95
24HAA2	7.43
48HAA2	5.96
4DAA2	4.69
5DAA2	3.55
7DAA2	2.51
14DAA2	1.82
21DAA2	0.85

DBA: days before application, DAA: days after application,
HAA: hours after application, HBA: hours before application,
LOD: level of detection (0.003 mg/kg)

C. Calculation of initial concentration (C₀) DT₅₀/DT₉₀ values

Sugar Beet Leaves

For sugar beet samples all of the models achieved the critical values < 15 for χ^2 -error and for the determination coefficient of $r^2 > 0.85$. The FOMC, DFOP and HS models showed either negative confidence intervals or were not statistically significant. For the SFO model the calculated χ^2 -error was 5.01 and the calculated r^2 was 0.97. The results of the calculation showed a DT₅₀ value of 10.81 days and a DT₉₀ value of 35.90 days, respectively.

Table A 2-46: Results and parameters of the kinetic degradation of zoxamide in/on sugar beet leaves (Trial S19-01450-01)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	10.81	10.33	10.37	10.96
DT ₉₀ [days]	35.90	43.62	38.68	35.98
CHI ² -err [%]	5.01	5.20	5.46	5.77
r ²	0.97	0.97	0.97	0.97
parameter	k = 0.064146	α = 3.5906	k1 = 0.33656	k1 = 0.0002994
	M(0) = 7.165004	β = 48.5250	k2 = 0.05661	k2 = 0.006432
		M(0) = 7.2753	g = 0.10653	tb = 0.1845
			M(0) = 7.34484	M(0) = 7.090
lower CI	k = 0.051628	α = -10.6976	k1 = -0.84082	k1 = -1.108
	M(0) = 6.732990	β = -171.3987	k2 = 0.02303	k2 = 0.04233
		M(0) = 6.6238	g = -0.32957	tb = -11.90
			M(0) = 6.68011	M(0) = 3.912
upper CI	k = 0.077	α = 17.879	k1 = 1.514	k1 = 1.109
	M(0) = 7.597	β = 268.449	k2 = 0.090	K = 0.086
		M(0) = 7.927	g = 0.543	tb = 12.267
			M(0) = 8.010	M(0) = 10.268
t-test	p(k): 2.82e-05	-	p(k1): 0.3026	p(k1): 0.49980
			p(k2): 0.0149	p(k2): 0.00229

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 α = $3.4735 \cdot N^{-0.8629}$
 β = $DT50 / (2^{(1/\alpha)} - 1)$
 N = $DT90 / DT50 - 3.32$
 DT₅₀ = estimated from the data
 DT₉₀ = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)
 k2 = rate constant for the slow degradation phase (ln(2)/DT50s)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Wheat Green Mass

For wheat samples all of the models achieved the critical values < 15 for χ^2 -error and for the determination coefficient of $r^2 > 0.85$. The FOMC, DFOP and HS models showed either negative confidence intervals or where not statistically significant. For the SFO model the calculated χ^2 -error was 5.44 and the calculated r^2 was 0.96. The results of the calculation showed a DT50 value of 5.44 days and a DT90 value of 18.06 days, respectively.

Table A 2-47: Results and parameters of the kinetic degradation of zoxamide in/on wheat green mass (Trial S19-01450-01)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	5.44	5.09	4.99	5.83
DT ₉₀ [days]	18.06	21.32	28.75	17.05
CHI ² -err [%]	9.00	9.06	9.48	8.83
r ²	0.96	0.96	0.96	0.97

parameter	k = 0.12751	$\alpha = 3.7007$	k1 = 1.599e-01	k1 = 1.149e-05
	M(0) = 7.56718	$\beta = 24.7017$	k2 = 2.868e-07	k2 = 1.435e-01
		M(0) = 7.7249	g = 9.091e-01	tb = 1.000
			M(0) = 7.736	M(0) = 7.027
lower CI	k = 0.09371	$\alpha = -6.2107$	k1 = 1.076e-02	k1 = -2.326e-01
	M(0) = 6.85027	$\beta = -51.9133$	k2 = -3.560e-01	k2 = 9.284e-02
		M(0) = 6.8304	g = 1.679e-01	tb = 1.998e-01
			M(0) = 6.733	M(0) = 5.780
upper CI	k = 0.161	$\alpha = 13.612$	k1 = 0.309	k1 = 0.233
	M(0) = 8.284	$\beta = 101.317$	k2 = 0.356	k2 = 0.194
		M(0) = 8.619	g = 1.650	tb = 1.800
			M(0) = 8.739	M(0) = 8.274
t-test	p(k): 0.000157	-	p(k1): 0.0517	p(k1): 0.499964
			p(k2): 0.5000	p(k2): 0.002574

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
 N = DT90/DT50-3.32
 DT50 = estimated from the data
 DT90 = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)
 k2 = rate constant for the slow degradation phase (ln(2)/DT50s)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

The following figures show residues of zoxamide.

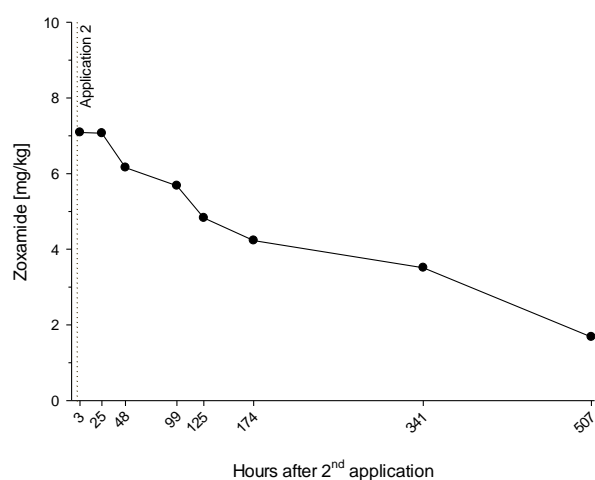


Figure A 11: Residues of zoxamide in sugar beet leaves over time (trial 01)

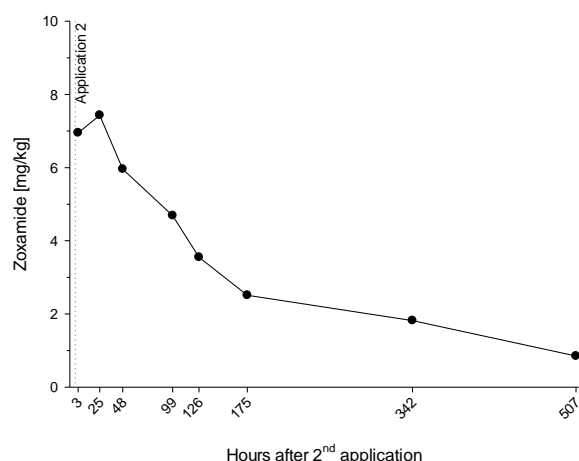


Figure A 12: Residues of zoxamide in wheat green mass over time (trial 01)

Conclusion

The residue decline of zoxamide on sugar beet leaves (as surrogate dicotyledonae plant) and wheat green mass (as surrogate monocotyledonae plant) has been studied in the field under representative growing conditions for Northern Europe (Netherlands). The degradation kinetics of the active ingredient were investigated after two applications of Zoxium 240 SC (240 g/L zoxamide, SC) at application rates for zoxamide of 180 g a.s./ha with an interval of 7 days (BBCH 18-21 for sugar beet and wheat).

The study was conducted in accordance to current guidelines.

For the degradation of zoxamide in sugar beet leaves, the single first order (SFO) degradation model was used – as recommended in Appendix H of the EFSA Birds and Mammals Guidance Document (2009). The DT50 value was calculated at 10.81 days and the DT90 was calculated at 35.90 days.

For the degradation of zoxamide in wheat green mass, the single first order (SFO) degradation model was used – as recommended in Appendix H of the EFSA Birds and Mammals Guidance Document (2009). The DT50 value was calculated at 5.44 days and the DT90 was calculated at 18.06 days.

(Appeltauer A. 2020)

A 2.9 Study 9 - Residue degradation of zoxamide in mono- and dicotyledonae plants under southern European growing conditions

Comments of zRMS:	The study was evaluated and accepted in Section 7.
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Reference: **KCP 9.2.5/04**

Report 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
Gowan Crop Protection Ltd., UK
Eurofins GmbH, Germany, Report No. S16-05376, GLP, Not published

Guideline(s): SANCO/4145/2000
EFSA Guidance on Risk Assessment for Birds and Mammals (2009)

SANCO/3029/99 rev. 4 (2000)
FOCUS (2014)

Deviations:	No daily precipitation GLP data available. Reason for this deviation was a mistake during study conduct. Amount of rain in rain gauge was only recorded at every visit (not daily). Only non-GLP rain data are available for the report.
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the residue decline of zoxamide on/in feed items of herbivorous birds and mammals under representative growing conditions in Southern Europe in the field: In sugar beet green mass (as surrogate dicotyledonae plant representative for the feed item group “non-grass herbs”) and in wheat green mass above soil (as surrogate monocotyledonae plant representative for the feed item group “grass and cereals”). The residues and degradation kinetics of the active ingredient were investigated after two applications of Zoxium 240 SC (240 g/L zoxamide, SC) at application rates for zoxamide of 180 g a.s./ha with an interval of 7 days (BBCH 15-29 for sugar beet and wheat). The early application timing of zoxamide to both plant groups is representative for the more sensitive phase of wild birds and mammals in nature.

The study consisted of three field trials, S16-05376-01 to -03 and one residue analytical phase, S16-05376-L1. The field parts were carried out in three fields located near Latnitsa (trial -01), Boshulya (trial -02) in Bulgaria and near Alpera (trial -03), in Spain. The field sites covered an area of approx. 255 m² sugar beet and 255 m² wheat (trial -01), approx. 270 m² sugar beet and 270 m² wheat (trial -02) and approx. 300 m² sugar beet and 300 m² wheat (trial -03).

Sugar beet plants were planted on 20 Mar 2017 (sugar beet) in trial -01, on 10 April 2017 in trial -02 and on 20 April 2017 in trial -03. Wheat was sown on 10 April 2017 in trial -01, on 10 April 2017 in trial -02 and on 20 April 2017 in trial -03. Samples were taken before each application and up to 16 days after the last application. One sampling before the 1st application served as control.

For the two specimen types, the sampling schedule was as follows: In trial -01, first sampling two days before the 1st application (control), 2 hours before the 2nd application, 2, 24, 48 hours after the 2nd application, and 5, 7, 8 and finally 16 days after the 2nd application. In trial -02, first sampling before the 1st application (control), 1 hour before the 2nd application, 2, 24, 48 hours after the 2nd application, and 4, 7, 8 and finally 16 days after the 2nd application. In trial -03, first sampling one day before the 1st application (control), directly before the 2nd application, 2, 24, 48 hours after the 2nd application, and 4, 6, 8 and finally 15 days after the 2nd application.

The samples were weighed in the field and frozen immediately on dry ice. Retained samples were taken for all matrices. All residues samples were stored in the freezer within 5 hours after collection in the field. The samples were stored and shipped frozen. At the testing sites (including shipment) the samples were stored deep frozen at $\leq -18^{\circ}\text{C}$ for a maximum of 101 days (sugar beet green mass) and 102 days (wheat green mass) until extraction and residue analysis. Residue analysis took place within 72 hours after extraction.

The method for the determination of zoxamide in sugar beet leaves and wheat green mass was validated according to SANCO Guideline 3029/99 rev. 4 in the analytical phase during the course of this study (EAS study number S16-05375 and CIP Phase ID 17E10095-02-RAVE). Specimens were extracted (in analogy to the QuEChERS multi residue method) with acetonitrile/water, phase separation was done by addition of buffer salt mixture. The final analysis was conducted with highly specific HPLC with MS/MS detection. Recoveries in the fortified samples were within the acceptable range of 70 - 110 %, therefore the stability of the analyte during storage of the final sample extracts is sufficiently proven.

The degradation kinetics of the active ingredient was analysed according to the recommendations of the

EFSA Guidance document on Risk Assessment for Birds and Mammals (2009) and the Guidance document on Estimating Persistence and Degradation Kinetics from Environmental Studies on Pesticides in EU Registration (FOCUS 2014). The calculation of the DT50 values and DT90 values as well as the fitting of the kinetic degradation models was done using the computer software KinGU II (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 operating system was Microsoft Windows 7 Professional.

Materials and methods

A. Materials

1. Test material	ZOXIUM 240 SC
Lot/batch:	SB 2401
Active substance content:	240 g/ zoxamide (nominal), 232 g/L zoxamide (analysed)
Expiry date:	April 2018

B. Methods

1. Experimental conditions

The study comprised three sugar beet and wheat fields, one per trial. All trials were treated with two applications of Zoxium 240 SC at a nominal rate of 180 g zoxamide/ha. Plot specifications (minimum distances and plot size) are given in Table 10 (Appendix A). The field sites were located near Letnitsa (trial -01) and Boshulya (trial -02) in Bulgaria and near Alpera (trial -03) in Spain. The agricultural practices and sugar beet varieties were in accordance with the local farming practices.

Each trial was designed to produce a single sample for each food type at each sampling date (i.e. to provide an assessment of the average residue level as well as to ensure sufficient material was collected for the actual residue analysis). To minimise edge effects from neighbouring fields, sampling was not carried out at the outer 50 cm of the field.

During the study weather data obtained from portable data loggers on the field sites and from weather stations in the vicinity of the field sites including precipitation and air temperature were taken. During application and samplings, the climatic conditions (GLP data) were measured at the field site with a portable thermo-hygrometer, a soil thermometer and a portable anemometer. Additional data for the long-term average were taken from official weather stations (non-GLP data).

No other formulations containing zoxamide were applied during the trial period onto the plot.

2. Sampling

Samples of different food items for birds and mammals were collected for residue analysis. Two categories of potential bird and mammalian food items were considered:

1. Sugar beet leaves / green mass
2. Wheat leaves / green mass

For each trial 9 samplings per category were carried out. The first sampling took place before the 1st application and was used as control sample.

For the two specimen types, the sampling schedule was as follows: In trial -01, first sampling two days before the 1st application (control), 2 hours before the 2nd application, 2, 24, 48 hours after the 2nd application, and 5, 7, 8 and finally 16 days after the 2nd application. In trial -02, first sampling before the 1st application (control), 1 hour before the 2nd application, 2, 24, 48 hours after the 2nd application,

and 4, 7, 8 and finally 16 days after the 2nd application. In trial -03, first sampling one day before the 1st application (control), directly before the 2nd application, 2, 24, 48 hours after the 2nd application, and 4, 6, 8 and finally 15 days after the 2nd application.

The samples were collected randomly on 12 locations per trial. There was at least 50 g plant material taken per field at each sampling occasion. Samplings were done by hand or with scissors. Samples were taken with a minimum distance of 0.5 m to the border of the plot. The samples of all locations of one field were put together to one pooled sample.

The samples were weighed in the field and frozen immediately on dry ice. Retained samples were taken for all matrices. All residues samples were stored in the freezer within 5 hours after collection in the field. The samples were stored and shipped frozen. At the testing sites (including shipment) the samples were stored deep frozen at $\leq -18^{\circ}\text{C}$ for a maximum of 101 days (sugar beet green mass) and 102 days (wheat green mass) until extraction and residue analysis.

3. Description of the analytical procedure

The data presented in this report demonstrate that the used method permits the determination of residues of zoxamide in sugar beet leaves (representing the feed item group “non-grass herbs”) and in wheat plants without roots (representing the feed item group “grass and cereals”) with accuracy, precision and repeatability. The method is based on QuEChERS multi-residue method, validated by RICHTER (2014) according to SANCO/825/00 rev. 8.1 for the determination of zoxamide in various crop commodities. This method was validated under the laboratory conditions of CIP for the determination of residues of zoxamide in sugar beet leaves and wheat plants according to guideline SANCO/3029/99 rev. 4. For this purpose, recovery experiments were performed by fortifying control (untreated) specimens.

10 g (± 0.1 g) of sugar beet leaves and wheat plant specimens were weighed into 50 mL single-use centrifuge tubes. Recovery samples were fortified at this step. 10 mL acetonitrile were added and the samples were homogenised for at least 2 min using a vortex mixer. Thereafter, QuEChERS EN15662 salt-mixture (1 g sodium citrate, 0.5 g sodium hydrogencitrate sesquihydrate, 4 g magnesium sulphate, 1 g sodium chloride) was added, thoroughly shaken and mixed again on a vortex mixer for at least 1 min. Residue analysis took place within 72 hours after extraction. The samples were centrifuged at 4000 min⁻¹ for at least 5 minutes. An aliquot of 1 mL of the supernatant was transferred into a tube prepared with 25 mg PSA (primary-secondary amino phase) and 150 mg anhydrous magnesium sulphate and mixed on a Vortex mixer for 1 min. The extract was filtered through a single-use syringe filter (0.45 μm) into an autosampler vial (1.8 mL). 0.5 mL of this solution were transferred into a second vial, 5 μL of acetonitrile + 5 % formic acid were added, the vial capped and thoroughly shaken. 50 μL of this sample extract were then diluted with 950 μL acetonitrile/water (20:80, v/v) plus 0.1 % formic acid. If necessary, these final extracts were diluted further with final extract of untreated samples to achieve final concentrations falling within the calibrated concentration range of the detection system.

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

4. Calculation of initial concentration (C₀) and DT₅₀/DT₉₀ values

The degradation time of zoxamide was calculated, including information about the kinetics of the decay according to the recommendations of the guidance document on estimating persistence and degradation kinetics from environmental studies on pesticides in EU registration (FOCUS 2014).

The calculation of the degradation of zoxamide residues in sugar beet leaves and wheat green mass was done based on the analysed residue data. The degradation kinetics of the active ingredient was analysed according to the recommendations of the EFSA Guidance document on Risk Assessment for Birds and Mammals (2009) and the Guidance document on Estimating Persistence and Degradation Kinetics from Environmental Studies on Pesticides in EU Registration (FOCUS 2014). The calculation of the DT₅₀ values and DT₉₀ values as well as the fitting of the kinetic degradation models was done using the

computer software KinGU II (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 operating system was Microsoft Windows 7 Professional.

For both commodities, the analysed residues after the last application (2nd application), i.e. starting from two or three hours after the last application to 15 to 16 days after the last application were chosen to establish degradation kinetics for the single trials. For the two commodities timings were calculated separately from the end of application until the samples were put on dry ice (i.e. time degradation of residues stops). Times were rounded to full hours.

Results and discussions

A. Weather conditions

The climatic conditions during trial -01 compared to the long-term average (1961-1990) revealed higher average temperatures for May and June 2017. During the trial period the rainfall recorded at the field site was 121 mm.

The climatic conditions during trial -02 compared to the long-term average (1961-1990) revealed slightly lower average temperatures for May 2017 and higher average temperatures for June 2017. During the trial period the rainfall recorded at the field site was 25 mm.

The climatic conditions during trial -03 compared to the long-term average (2000-2017) revealed higher average temperatures for May and June 2017. During the trial period the rainfall recorded at the field site was 25 mm.

B. Zoxamide residues

In the control samples, taken directly before the 1st application, concentrations analysed were below the LOD (0.003 mg/kg) in all trials.

Zoxamide in/on sugar beet leaves

Zoxamide concentrations in sugar beet leaves of the three trials shortly before the 2nd application (0-2 HBA2) were 0.47 mg/kg (trial -01), 1.85 mg/kg (trial -02), and 0.77 mg/kg (trial 03). The highest concentrations were analysed two hours after the 2nd application in trial -01 and 24 hours after the 2nd application in trial -02 and -03 (trial -01: 9.48 mg/kg; trial -02: 11.1 mg/kg, trial -03: 7.55 mg/kg). At the last sampling 15/16DAA2 concentrations for the field trials were 0.08 mg/kg (trial -01), 0.69 mg/kg (trial -02) and 0.76 mg/kg (trial -03). In trial -01, analysed zoxamide concentrations increased to a peak of 9.48 mg/kg at 2HAA2 and decreased subsequently until the last sampling (16DAA2) when 0.08 mg/kg were measured. In trial -02 the highest concentrations of all trials were analysed for zoxamide. Highest concentrations were measured 24 hours after the 2nd application with 11.1 mg/kg. Concentrations decreased in the following samplings to 0.69 mg/kg at 16DAA2. In trial -03, analysed zoxamide concentrations increased to a peak of 7.55 mg/kg at 24HAA2 and decreased subsequently until the last sampling (15DAA2) when 0.76 mg/kg were measured. A summary of the residue levels found in sugar beet leaves samples is shown in the following table.

Table A 2-48: Zoxamide residues in/on sugar beet leaves (individual values of all field sites)

Timing (trial -01/-02/-03)	Trial		
	-01	-02	-03
	[mg/kg]	[mg/kg]	[mg/kg]
2/0/1DBA1	<LOD	<LOD	<LOD
2/1/0HBA2	0.47	1.85	0.77

2/3/3HAA2	9.48	10.2	6.53
24/24/24HAA2	9.11	11.1	7.55
48/49/48HAA2	9.08	10.2	4.83
5/4/4DAA2	1.28	7.53	1.97
7/7/6DAA2	1.12	4.31	1.57
8/8/8DAA2	0.78	3.14	1.49
16/16/15DAA2	0.08	0.69	0.76

DBA: days before application, DAA: days after application,
HAA: hours after application, HBA: hours before application,
LOD: level of detection (0.003 mg/kg)

Zoxamide in/on wheat green mass

In the control samples, taken directly before the 1st application, concentrations analysed were below the LOD (0.003 mg/kg) in all trials. zoxamide concentrations in wheat green mass shortly before the 2nd application (0-2 HBA2) were 0.52 mg/kg (trial -01), 1.42 mg/kg (trial -02) and 1.76 mg/kg (trial -03). The highest concentrations were analysed two hours after the 2nd application in trial -01, -02 and -03 (trial -01: 7.97 mg/kg, trial -02: 7.66 mg/kg, trial -03: 5.83 mg/kg). At the last sampling 15/16DAA2 concentrations for the field trials were 0.02 mg/kg (trial -01), 0.51 mg/kg (trial -02) and 2.02 mg/kg (trial -03). In trial -01, analysed zoxamide concentrations in wheat green mass, increased to 7.97 mg/kg two hours after the 2nd application (2HAA2). In subsequent samplings concentrations decreased to 0.02 mg/kg at 16DAA2. In trial -02 concentrations of zoxamide in wheat green mass increased to 7.66 mg/kg two hours after the 2nd application (2HAA2). At the following two samplings (24 and 48HAA2) concentrations decreased to 5.44 mg/kg followed by a slight increase to 5.59 mg/kg at 4DAA2. In sampling 7DAA2 concentrations decreased to 2.42 mg/kg again followed by an increase to 4.12 mg/kg. At the last sampling 16DAA2 concentrations decreased to 0.51 mg/kg. In trial -03 the highest concentration was analysed at 2HAA2 with 5.83 mg/kg. Afterwards concentrations decreased to 2.02 mg/kg at 15DAA2. A summary of the residue levels found in cereal green mass samples is shown in the following table.

Table A 2-49: Zoxamide residues in/on wheat green mass (individual values of all field sites)

Timing (trial -01/-02/-03)	Trial		
	-01	-02	-03
	[mg/kg]	[mg/kg]	[mg/kg]
2/0/1DBA1	<LOD	<LOD	<LOD
2/1/0HBA2	0.52	1.42	1.76
2/3/3HAA2	7.97	7.66	5.83
24/24/24HAA2	5.56	5.81	5.37
48/49/48HAA2	5.27	5.44	5.23
5/4/4DAA2	1.60	5.59	3.00
7/7/6DAA2	1.15	2.42	2.74
8/8/8DAA2	0.39	4.12	2.74
16/16/15DAA2	0.02	0.51	2.02

DBA: days before application, DAA: days after application,
HAA: hours after application, HBA: hours before application,
LOD: level of detection (0.003 mg/kg)

C. Calculation of initial concentration (C0) DT50/DT90 values

Sugar Beet Leaves

In trial -02 the calculation of degradation rates for zoxamide in sugar beet leaves achieved critical values < 15 for χ^2 -error for all models. In trials -01 and -03 none of the models achieved the critical values < 15 for

χ^2 -error. The determination coefficient of $r^2 > 0.85$ was achieved for all trials and for all models. In trial -01 the visual fit of the DFOP model was better than for the SFO model. However, the confidence intervals of the DFOP model showed negative values and $p(k_2)$ was not statistically significant. Therefore, the DFOP model was not appropriate for the residue data. In trial -02 the HS model showed lowest χ^2 -error and the highest r^2 with 0.99. But the HS model was not appropriate because the confidence intervals revealed negative values and $p(k_1)$ was not statistically significant (> 0.05). In trial -03 all three biphasic models (FOMC, DFOP and HS) were not appropriate because of negative values within the confidence intervals. Therefore, for all three trials the SFO model was used for calculation of degradation rates of zoxamide in sugar beet leaves. The results of the calculation showed DT50 values between 2.60 and 5.02 days and DT90 values between 8.64 and 16.67 days, respectively for the degradation of zoxamide in sugar beet leaves. The calculated χ^2 -errors for the three trials were 23.80, 10.74 and 18.22 for trials -01, -02 and -03, respectively. The calculated r^2 for the three trials were 0.90, 0.94 and 0.90 (SFO) for trials -01, -02 and -03, respectively.

Table A 2-50: Results and parameters of the kinetic degradation of zoxamide in/on sugar beet leaves (Trial S16-05376-01)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	2.60	1.70	2.60	2.60
DT ₉₀ [days]	8.64	5.64	8.64	8.64
CHI ² -err [%]	23.80	33.21	28.33	28.33
r ²	0.90	0.85	0.90	0.90
parameter	k = 0.26655	$\alpha = 1133.445$	k ₁ = 0.26655	k ₁ = 0.26655
	M(0) = 11.11148	$\beta = 2771.880$	k ₂ = 0.07474	k ₂ = 0.15911
		M(0) = 12.227	g = 1.00000	tb = 16.04790
			M(0) = 11.11147	M(0) = 11.11147
lower CI	k = 0.14017	$\alpha = -26834.081$	k ₁ = 0.08845	k ₁ = 0.10511
	M(0) = 8.51574	$\beta = -65653.126$	k ₂ = -1.57811	k ₂ = 0.04712
		M(0) = 8.301	g = -0.72896	tb = -18.42802
			M(0) = 5.96783	M(0) = 7.98092
upper CI	k = 0.393	$\alpha = 29100.97$	k ₁ = 0.445	k ₁ = 0.428
	M(0) = 13.707	$\beta = 71196.89$	k ₂ = 1.728	k ₂ = 0.271
		M(0) = 16.15	g = 2.729	tb = 50.524
			M(0) = 16.255	M(0) = 14.242
t-test	p(k): 0.004525	-	p(k ₁): 0.0304	p(k ₁): 0.02400
			p(k ₂): 0.4675	p(k ₂): 0.03436

SFO = Single first order kinetic;
FOMC = First order multi compartment kinetic;
DFOP = Double first order kinetic;
HS = Hockey stick kinetic
M(0) = initial concentration
CI = confidence interval
t = time after time of initial concentration
k = rate constant ($\ln(2)/DT_{50}$)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT_{50}/(2^{1/\alpha} - 1)$
N = $DT_{90}/DT_{50} - 3.32$
DT₅₀ = estimated from the data
DT₉₀ = estimated from the data
k₁ = rate constant for the fast degradation phase ($\ln(2)/DT_{50f}$)
k₂ = rate constant for the slow degradation phase ($\ln(2)/DT_{50s}$)
tb = break point time estimated from the data rate
g = 1-F
F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Table A 2-51: Results and parameters of the kinetic degradation of zoxamide in/on sugar beet leaves (Trial S16-05376-02)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	5.02	5.49	5.02	5.65
DT ₉₀ [days]	16.67	18.25	16.67	14.38
CHI ² -err [%]	10.74	11.98	12.79	4.32
r ²	0.94	0.95	0.94	0.99
parameter	k = 0.13813	α = 1966	k1 = 0.13813	k1 = 6.915e-09
	M(0) = 11.92396	β = 15580	k2 = 0.06732	k2 = 0.1844
		M(0) = 11.64	g = 1.00000	tb = 1.893
			M(0) = 11.92394	M(0) = 10.65
lower CI	k = 0.09551	α = -1008	k1 = -0.23822	k1 = -0.4135
	M(0) = 10.35633	β = -7987	k2 = -0.88271	k2 = 0.1522
		M(0) = 10.15	g = -2.07191	tb = -1.144
			M(0) = 9.48538	M(0) = 8.135
upper CI	k = 0.181	α = 14008.41	k1 = 0.514	k1 = 0.413
	M(0) = 13.492	β = 111023.55	k2 = 1.017	k2 = 0.217
		M(0) = 13.12	g = 4.072	tb = 4.930
			M(0) = 14.363	M(0) = 13.165
t-test	p(k): 0.000714	-	p(k1): 0.26195	p(k1): 0.500
			p(k2): 0.44917	p(k2): 0.000758

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 α = $3.4735 \cdot N^{-0.8629}$
 β = $DT50 / (2^{(1/\alpha)} - 1)$
 N = $DT90 / DT50 - 3.32$
 DT₅₀ = estimated from the data
 DT₉₀ = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)
 k2 = rate constant for the slow degradation phase (ln(2)/DT50s)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Table A 2-52: Results and parameters of the kinetic degradation of zoxamide in/on sugar beet leaves (Trial S16-05376-03)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	2.89	2.87	2.74	2.72
DT ₉₀ [days]	9.60	9.55	11.19	14.91
CHI ² -err [%]	18.22	19.68	21.24	20.45
r ²	0.90	0.90	0.90	0.91
parameter	k = 0.23973	α = 282.0	k1 = 0.2755	k1 = 0.25437
	M(0) = 7.66682	β = 1165	k2 = 7.951e-08	k2 = 0.08713
		M(0) = 7.684	g = 0.9432	tb = 6.00000
			M(0) = 7.763	M(0) = 7.76221
lower CI	k = 0.13219	α = -6331	k1 = -0.06204	k1 = 0.11551
	M(0) = 6.04061	β = -26250	k2 = -1.775	k2 = -0.35909

		M(0) = 6.173	g = -0.2244	tb = -7.43117
			M(0) = 5.608	M(0) = 5.71589
upper CI	k = 0.347	α = 6895.135	k1 = 0.613	k1 = 0.393
	M(0) = 9.293	β = 28582.483	k2 = 1.775	k2 = 0.533
		M(0) = 9.196	g = 2.111	tb = 19.431
			M(0) = 9.918	M(0) = 9.809
t-test	p(k): 0.003614	-	p(k1): 0.10398	p(k1): 0.01851
			p(k2): 0.500	p(k2): 0.36372

SFO = Single first order kinetic;

FOMC = First order multi compartment kinetic;

DFOP = Double first order kinetic;

HS = Hockey stick kinetic

M(0) = initial concentration

CI = confidence interval

t = time after time of initial concentration

k = rate constant (ln(2)/DT50)

α = $3.4735 \cdot N^{-0.8629}$

β = $DT50 / (2^{(1/\alpha)} - 1)$

N = $DT90 / DT50 - 3.32$

DT₅₀ = estimated from the data

DT₉₀ = estimated from the data

k1 = rate constant for the fast degradation phase (ln(2)/DT50f)

k2 = rate constant for the slow degradation phase (ln(2)/DT50s)

tb = break point time estimated from the data rate

g = 1-F

F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Wheat Green Mass

In trials -01 to -03 the calculation of degradation rates for zoxamide in wheat green mass showed critical values < 15 for χ^2 -error for the SFO model. For all models the determination coefficient of r^2 was higher than 0.85. As the t-test of the SFO model for all trials was statistically significant ($p(k) < 0.05$) the SFO model was used to calculate the degradation rates of all trials. The results of the calculation showed DT50 values between 2.35 and 6.94 days and DT90 values between 7.80 and 23.04 days, respectively for the degradation of zoxamide in wheat green mass. The calculated χ^2 -errors for the three trials were 9.83, 13.91 and 10.44 for trials -01, -02 and -03, respectively. The calculated r^2 for the three trials were 0.98, 0.87 and 0.88 for trials -01, -02 and -03, respectively.

Table A 2-53: Results and parameters of the kinetic degradation of zoxamide in/on wheat green mass (Trial S16-05376-01)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	2.35	2.15	2.35	2.61
DT ₉₀ [days]	7.80	7.15	7.80	7.19
CHI ² -err [%]	9.83	11.31	11.70	9.98
r^2	0.98	0.98	0.98	0.99
parameter	k = 0.29527	α = 2926.7619	k1 = 0.29527	k1 = 0.23865
	M(0) = 8.13430	β = 9079.6642	k2 = 0.08440	k2 = 0.35174
		M(0) = 8.3194	g = 1.00000	tb = 2.00000
			M(0) = 8.13432	M(0) = 7.85397
lower CI	k = 0.23309	α = -2435.3737	k1 = 0.10916	k1 = 0.11678
	M(0) = 7.37933	β = -7562.7069	k2 = 0.06279	k2 = 0.01787
		M(0) = 7.4606	g = 0.52738	tb = -10.41645
			M(0) = 7.01281	M(0) = 6.88518
upper CI	k = 0.357	α = 8288.898	k1 = 0.481	k1 = 0.361
	M(0) = 8.889	β = 25722.035	k2 = 0.106	k2 = 0.686

		M(0) = 9.178	g = 1.473	tb = 14.416
			M(0) = 9.256	M(0) = 8.823
t-test	p(k): 0.000121	-	p(k1): 0.026449	p(k1): 0.015594
			p(k2): 0.002317	p(k2): 0.065443

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
 N = DT90/DT50-3.32
 DT50 = estimated from the data
 DT90 = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)
 k2 = rate constant for the slow degradation phase (ln(2)/DT50s)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Table A 2-54: Results and parameters of the kinetic degradation of zoxamide in/on wheat green mass (Trial S16-05376-02)

Model	SFO	FOMC	DFOP	HS
DT₅₀ [days]	6.19	5.39	6.19	6.68
DT₉₀ [days]	20.57	17.93	20.57	17.98
CHI²-err [%]	13.91	15.59	16.56	15.84
r²	0.87	0.87	0.87	0.88
parameter	k = 0.11194	$\alpha = 620.7$	k1 = 0.11195	k1 = 0.08008
	M(0) = 7.31253	$\beta = 4823$	k2 = 0.11193	k2 = 0.14244
		M(0) = 7.564	g = 0.70471	tb = 4.14381
			M(0) = 7.31256	M(0) = 7.01999
lower CI	k = 0.06184	$\alpha = -12880$	k1 = -0.02011	k1 = -0.06658
	M(0) = 6.01954	$\beta = -100100$	k2 = -0.23785	k2 = -0.07974
		M(0) = 6.276	g = -1.79763	tb = -11.61031
			M(0) = 5.69192	M(0) = 5.07482
upper CI	k = 0.162	$\alpha = 14120$	k1 = 0.244	k1 = 0.227
	M(0) = 8.606	$\beta = 109800$	k2 = 0.462	k2 = 0.365
		M(0) = 8.852	g = 3.207	tb = 19.898
			M(0) = 8.933	M(0) = 8.965
t-test	p(k): 0.00358	-	p(k1): 0.09761	p(k1): 0.18150
			p(k2): 0.28750	p(k2): 0.14893

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
 N = DT90/DT50-3.32
 DT50 = estimated from the data
 DT90 = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)

k2 = rate constant for the slow degradation phase ($\ln(2)/DT50s$)
tb = break point time estimated from the data rate
g = 1-F
F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

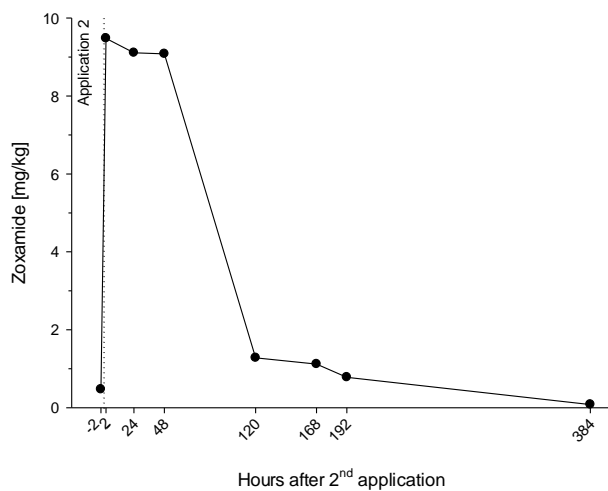
Table A 2-55: Results and parameters of the kinetic degradation of zoxamide in/on wheat green mass (Trial S16-05376-03)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	6.94	5.73	5.32	6.99
DT ₉₀ [days]	23.04	62.53	n.a.	23.09
CHI ² -err [%]	10.44	8.76	8.76	12.43
r ²	0.88	0.93	0.94	0.88
parameter	k = 0.09993	α = 0.8608	k1 = 0.2349	k1 = 0.02609
	M(0) = 5.79592	β = 4.6269	k2 = 1.179e-07	k2 = 0.09993
		M(0) = 6.1990	g = 0.7008	tb = 0.07029
			M(0) = 6.205	M(0) = 5.76592
lower CI	k = 0.05761	α = -0.3385	k1 = -0.1460	k1 = -0.06720
	M(0) = 4.98950	β = -5.7636	k2 = -0.2139	k2 = 0.04430
		M(0) = 5.1972	g = -0.3177	tb = -2.44704
			M(0) = 5.255	M(0) = 4.30653
upper CI	k = 0.142	α = 2.060	k1 = 0.616	k1 = 0.119
	M(0) = 6.602	β = 15.018	k2 = 0.214	k2 = 0.156
		M(0) = 7.201	g = 1.719	tb = 2.588
			M(0) = 7.155	M(0) = 7.225
t-test	p(k): 0.00285	-	p(k1): 0.156697	p(k1): 0.31088
			p(k2): 0.500	p(k2): 0.01945

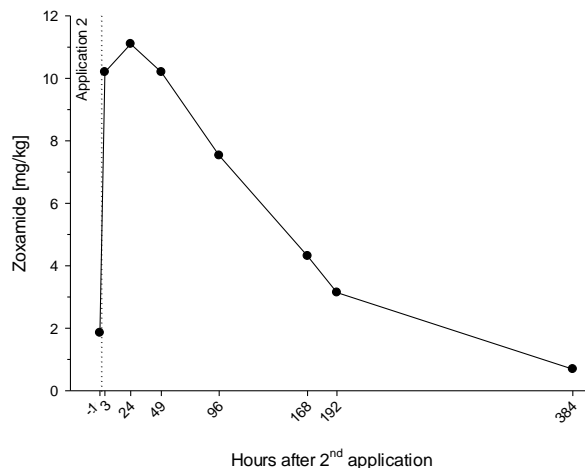
SFO = Single first order kinetic;
FOMC = First order multi compartment kinetic;
DFOP = Double first order kinetic;
HS = Hockey stick kinetic
M(0) = initial concentration
CI = confidence interval
t = time after time of initial concentration
k = rate constant ($\ln(2)/DT50$)
 α = $3.4735 \cdot N^{-0.8629}$
 β = $DT50 / (2^{(1/\alpha)} - 1)$
N = $DT90/DT50 - 3.32$
DT50 = estimated from the data
DT90 = estimated from the data
k1 = rate constant for the fast degradation phase ($\ln(2)/DT50f$)
k2 = rate constant for the slow degradation phase ($\ln(2)/DT50s$)
tb = break point time estimated from the data rate
g = 1-F
F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

The following figures show residues of zoxamide.

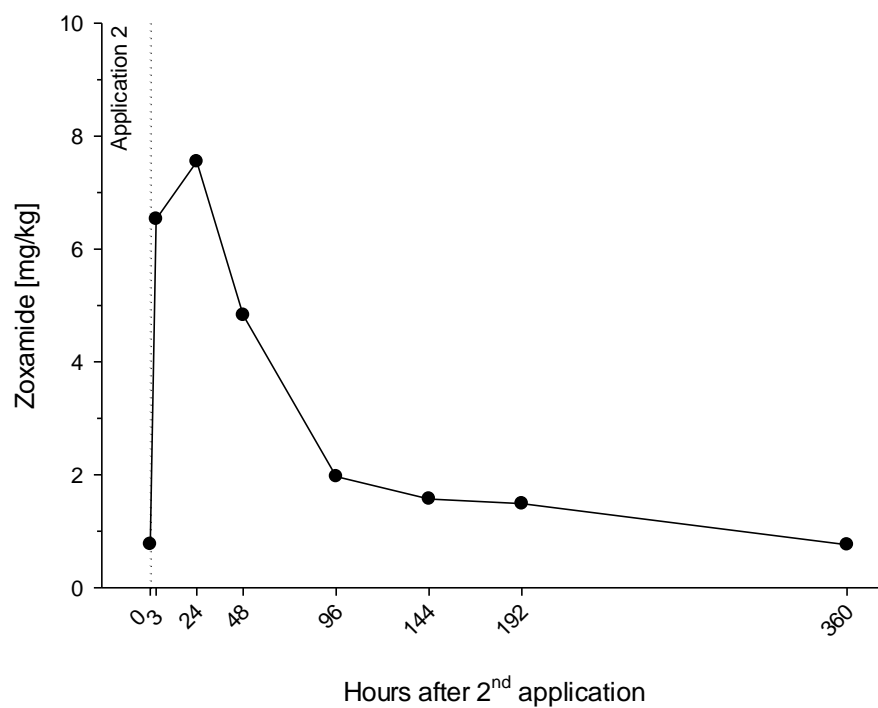
Sugar beet leaves



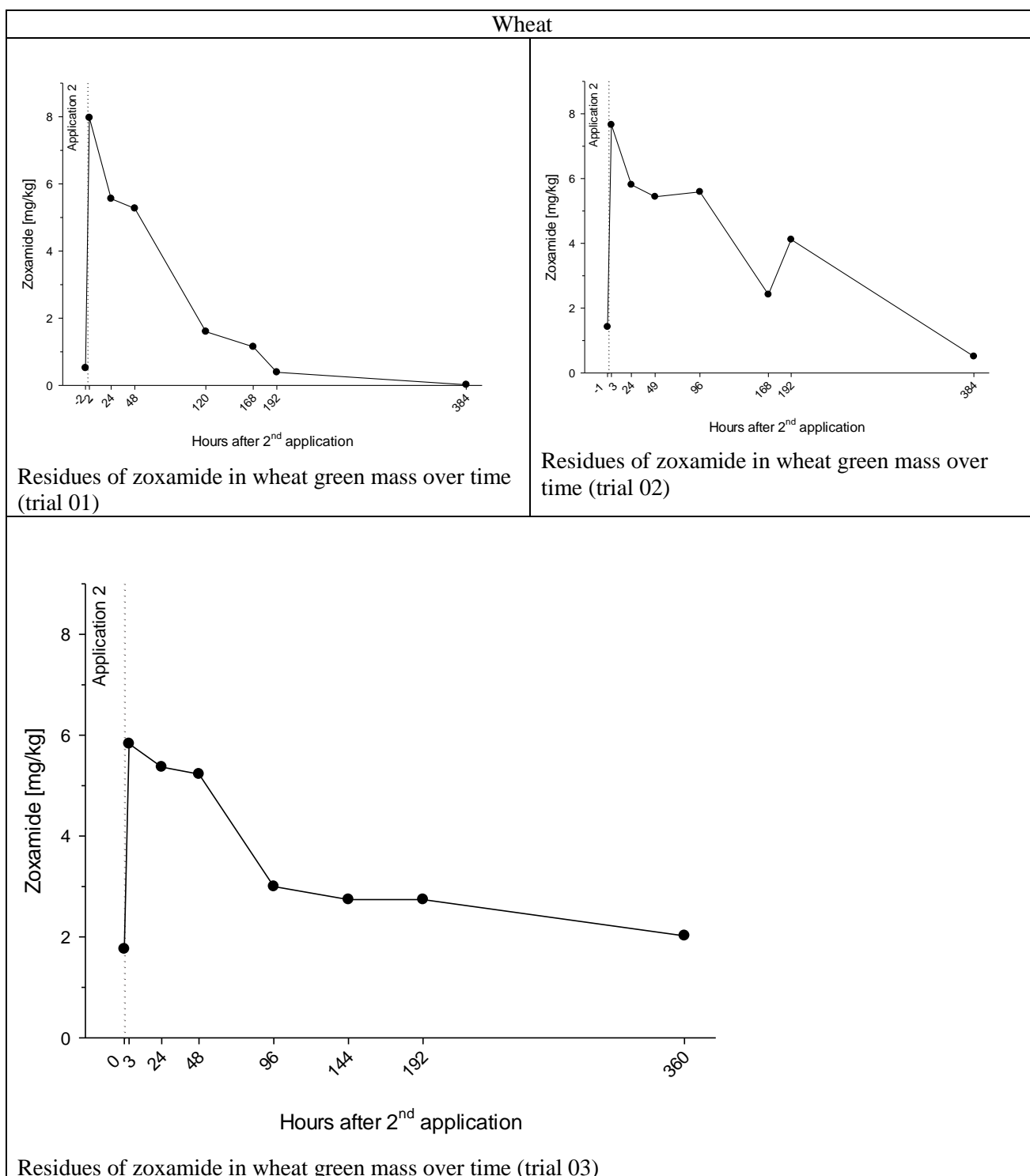
Residues of zoxamide in sugar beet leaves over time (trial 01)



Residues of zoxamide in sugar beet leaves over time (trial 02)



Residues of zoxamide in sugar beet leaves over time (trial 03)



Conclusion

The residue decline of zoxamide on sugar beet leaves (as surrogate dicotyledonae plant) and wheat green mass (as surrogate monocotyledonae plant) has been studied in the field under representative growing conditions for Southern Europe. The residues and degradation kinetics of the active ingredient were investigated after two applications of Zoxium 240 SC (240 g/L zoxamide, SC) at application rates for zoxamide of 180 g a.s./ha with an interval of 7 days (BBCH 15-29 for sugar beet and wheat).

The resulting SFO DT50 values for all three trials on sugar beet performed under southern European growing conditions were calculated between 2.60 and 5.02 days and DT90 values were calculated between

8.64 and 16.67 days. For wheat green mass the single first order (SFO) DT50 values were calculated between 2.35 and 6.94 days and DT90 values were calculated between 7.80 and 23.04 days.

The study was conducted in accordance to current guidelines.

(Appeltauer A. 2020)

A 2.10 Study 10 - Residue degradation of zoxamide in mono- and dicotyledonae plants under southern European growing conditions

Comments of zRMS:	The study was evaluated and accepted in Section 7.
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Reference: **KCP 9.2.5/05**

Report 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 Italy in 2020
Gowan Crop Protection Ltd., UK
Eurofins GmbH, Germany, Report No. S19-23773, GLP, Not published

Guideline(s): SANCO/4145/2000
EFSA Guidance on Risk Assessment for Birds and Mammals (2009)
SANCO/3029/99 rev. 4
SANCO/825/00 rev. 8.1
EFSA Technical Report (2019): Outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods.
FOCUS (2014)

Deviations: No
GLP: Yes
Acceptability: Yes

The objective of this study was to determine the residue decline of zoxamide on/in feed items of herbivorous birds and mammals under representative growing conditions in Italy in the field: In sugar beet leaves (as surrogate dicotyledonae, representative for the feed item group “non-grass herbs”) and in wheat green mass above soil (as surrogate monocotyledonae, representative for the feed item group “grass and cereals”). The residues and degradation kinetics of the active ingredient were investigated after two applications of Zoxium 240 SC (240 g/L zoxamide, SC) at application rates for zoxamide of 180 g a.i./ha with an interval of 7 days (BBCH 17-21 for sugar beet and wheat).

The study consisted of one field trial, S19-23773-01 and one residue analysis trial, S19-23773-L1. The field part was carried out on a field located near Mezzolara, Bologna, Italy. The field site of the trial covered an area of 540 m² sugar beet and 540 m² summer wheat. Sugar beet plants were planted on 11 Mar 2020; wheat was sown on 24 Feb 2020.

For the two specimen types, the sampling schedule was as follows: the first sampling before the 1st application (control), 1 hour before 2nd application, 3, 24, 48 hours after the 2nd application, and 4, 7, 9 and finally 15 days after the 2nd application. One sampling before the 1st application served as control.

All residues samples were stored in the freezer within 3 hours after collection in the field. The samples were stored and shipped frozen. The maximum storage time of samples was 30 days for sugar beet leaves and 31

days for wheat green mass (control samples: 37 days for sugar beet leaves and 38 days for wheat green mass) until extraction and residue analysis. Residue analysis took place within 1 day after extraction. Retained samples were taken for all matrices.

The residues of the active ingredients on/in sugar beet leaves and wheat green mass were analysed with fully validated analytical methods according to SANCO/3029/99 rev. 4. The method has previously been validated in a study of Witte A. (CIP Phase ID 17E10095-01-RAVE, analytical part of EAS study S16-05375) at an LOQ of 0.01 mg/kg for the matrices under investigation. It takes into account additional requirements of SANCO/825/00 rev. 8.1 and EFSA Technical Report (2019): Outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. Specimens were extracted (in analogy to the QuEChERS multi residue method) with acetonitrile/water, phase separation was done by addition of buffer salt mixture. The final analysis was conducted with highly specific HPLC with MS/MS detection. Recoveries in the fortified samples were within the acceptable range of 70 - 110 %, therefore the stability of the analyte during storage of the final sample extracts is sufficiently proven.

The degradation kinetics of the active ingredient was analysed according to the recommendations of the EFSA Guidance document on Risk Assessment for Birds and Mammals (2009) and the Guidance document on Estimating Persistence and Degradation Kinetics from Environmental Studies on Pesticides in EU Registration (FOCUS 2014). The calculation of the DT50 values and DT90 values as well as the fitting of the kinetic degradation models was done using the computer software KinGU II (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 operating system was Microsoft Windows 10 Professional.

Materials and methods

A. Materials

1. Test material	ZOXIUM 240 SC
Lot/batch:	18011201-72-52
Active substance content:	21.8% w/w (240 g/ zoxamide nominal), 21.49% zoxamide (analysed)
Expiry date:	January 2022

B. Methods

1. Experimental conditions

The study comprised one sugar beet and wheat field, trial S19-23773-01. The trial was treated with two applications of Zoxium 240 SC at a nominal rate of 180 g zoxamide/ha. Plot specifications (minimum distances to the edge of the field and plot size) are given in Table 6 (Appendix A). The field site was located near Mezzolara, Bologna, in Italy. The agricultural practices and sugar beet / wheat varieties were in accordance with the local farming practice.

The trial was designed to produce a single sample for each food type at each sampling date (i.e. to provide an assessment of the average residue level as well as to ensure that sufficient material was collected for the actual residue analysis). To minimise edge effects from neighbouring fields, sampling was not carried out at the outer 50 cm of the plot.

During the study, weather data obtained from weather equipment placed on the field site including precipitation and air temperature was taken (GLP data). During applications and samplings, the climatic

conditions (GLP data) were measured at the field site with a portable thermo-hygrometer, a soil thermometer and a portable anemometer.

No other formulations containing zoxamide were applied during the trial period onto the plot.

2. Sampling

Samples of different food items for birds and mammals were collected for residue analysis. Two categories of potential bird and mammalian food items were considered:

1. Sugar beet leaves
2. Wheat

For each trial 9 samplings per category were carried out. The first sampling took place before the 1st application and was used as control sample.

For the two specimen types, the sampling schedule was as follows: the first sampling before the 1st application (control), 1 hour before 2nd application, 3, 24, 48 hours after the 2nd application, and 4, 7, 9 and finally 15 days after the 2nd application. One sampling before the 1st application served as control.

The specimens were sampled randomly on at least 12 locations per sample. There were at least 500 g plant material taken at each sampling occasion. Samplings were done by hand or with a knife. Samples were taken with a minimum distance of 0.5 m to the border of the plot. The samples of all locations of one field were put together to one pooled sample per sampling occasion.

All residues samples were weighed and stored in the freezer within 3 hours after collection in the field. The samples were stored and shipped frozen until extraction and residue analysis. Retained samples were taken for all matrices.

3. Description of the analytical procedure

The data presented in this report demonstrate that the used method permits the determination of residues of zoxamide in in sugar beet leaves and in wheat plants with accuracy, precision and repeatability. The method is based on QuEChERS multi-residue method, validated by RICHTER (2014) according to SANCO/825/00 rev. 8.1 for the determination of zoxamide in various crop commodities. This method was validated under the laboratory conditions of CIP for the determination of residues of zoxamide in sugar beet leaves and wheat green mass according to guideline SANCO/3029/99 rev. 4. For this purpose, recovery experiments were performed by fortifying control (untreated) specimens.

10 g (\pm 0.1 g) of sugar beet leaves and wheat plant specimens were weighed into 50 mL singleuse centrifuge tubes. Recovery samples were fortified at this step. 10 mL acetonitrile were added and the samples were homogenised for at least 2 min using a vortex mixer. Thereafter, QuEChERS EN15662 salt-mixture (1 g sodium citrate, 0.5 g sodium hydrogencitrate sequihydrate, 4 g magnesium sulphate, 1 g sodium chloride) was added, thoroughly shaken and mixed again on a vortex mixer for at least 1 min. The samples were centrifuged at 4000 min⁻¹ for at least 5 minutes. An aliquot of 1 mL of the supernatant was transferred into a tube prepared with 25 mg PSA (primary-secondary amino phase) and 150 mg anhydrous magnesium sulphate and mixed on a Vortex mixer for 1 min. The extract was filtered through a single-use syringe filter (0.45 μ m) into an autosampler vial (1.8 mL). 0.5 mL of this solution were transferred into a second vial, 5 μ L of acetonitrile + 5 % formic acid were added, the vial capped and thoroughly shaken. 50 μ L of this sample extract were then diluted with 950 μ L acetonitrile/water (20:80, v/v) plus 0.1 % formic acid. If necessary, these final extracts were diluted further with final extract of unfortified control samples to achieve final concentrations falling within the calibrated concentration range of the detection system.

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

4. Calculation of initial concentration (C0) DT50/DT90 values

The calculation of the degradation of zoxamide residues in sugar beet leaves and wheat green mass was done based on the analysed residue data.

The degradation kinetics of the active ingredient was analysed according to the recommendations of the EFSA Guidance document on Risk Assessment for Birds and Mammals (2009) and the Guidance document on Estimating Persistence and Degradation Kinetics from Environmental Studies on Pesticides in EU Registration (FOCUS 2014).

The calculation of the DT50 values and DT90 values as well as the fitting of the kinetic degradation models was done using the computer software KinGU II (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 operating system was Microsoft Windows 10 Professional.

For both commodities, the analysed residues after the last application (2nd application), i.e. starting from three hours after the last application to 15 days after the last application were chosen to establish degradation kinetics. For the two commodities timings were calculated separately from the end of application until the samples were put on dry ice (i.e. time degradation of residues stops). Times were rounded to days (2 digits). For wheat samples the exact timing of 2.53 hours was used to calculate the of 0.11 days. For the tables in the report the rounded value is given with 3 hours.

Results and discussions

A. Weather conditions

During the trial period the daily average temperatures were between 19.0 °C and 27.8 °C. The rainfall recorded at the field site was 7 mm during the period from first sampling before application to last sampling.

B. Zoxamide residues

In the control samples, taken directly before the 1st application, concentrations analysed were below the LOD (0.003 mg/kg) in all trials.

Zoxamide in/on sugar beet leaves

Zoxamide concentrations in sugar beet leaves were highest at the first sampling after the 2nd application (3HAA2) with 11.4 mg/kg. Subsequently residues decreased to 2.82 mg/kg at the last sampling (15DAA2), with a second smaller peak (7.27 mg/kg) at sampling S6 (4DAA2). A summary of the residue levels found in sugar beet leaf samples is shown in the following table.

Table A 2-56: Zoxamide residues in/on sugar beet leaves

Timing	Trial
	S19-23773-01
	[mg/kg]
0DBA1	<LOD
1HBA2	2.04
3HAA2	11.4
24HAA2	8.24
48HAA2	6.93
4DAA2	7.27
7DAA2	5.65
9DAA2	3.27
15DAA2	2.82

DBA: days before application, DAA: days after application,
HAA: hours after application, HBA: hours before application,

LOD: level of detection (0.003 mg/kg)

Zoxamide in/on wheat green mass

Zoxamide concentrations in wheat samples were at 9.58 mg/kg at the first sampling after the 2nd application (3HAA2). Subsequently residues decreased to 0.941 mg/kg at the last sampling (15DAA2). A summary of the residue levels found in wheat green mass samples is shown in the following table.

Table A 2-57: Zoxamide residues in/on wheat green mass

Timing	Trial
	S19-23773-01
	[mg/kg]
0DBA1	<LOD
1HBA2	1.92
3HAA2	9.58
24HAA2	7.97
48HAA2	6.98
4DAA2	4.64
7DAA2	4.06
9DAA2	2.30
15DAA2	0.941

DBA: days before application, DAA: days after application,
HAA: hours after application, HBA: hours before application,
LOD: level of detection (0.003 mg/kg)

Sugar Beet Leaves

For sugar beet samples all of the models achieved the critical values < 15 for χ^2 -error and for the determination coefficient of $r^2 > 0.85$. The FOMC and DFOP models showed either negative confidence intervals or were not statistically significant. The HS and the SFO model showed no negative confidence intervals and were statistically significant. For the SFO model the calculated χ^2 -error was 11.57 and the calculated r^2 was 0.88. The results of the calculation for the SFO model showed a DT50 value of 6.86 days and a DT90 value of 22.78 days, respectively.

Table A 2-58: Results and parameters of the kinetic degradation of zoxamide in/on sugar beet leaves (Trial S19-23773-01)

Model	SFO	FOMC	DFOP	HS
DT ₅₀ [days]	6.86	4.37	3.60	4.93
DT ₉₀ [days]	22.78	111.40	23.73	25.14
CHI ² -err [%]	11.57	10.80	8.76	8.76
r ²	0.88	0.91	0.95	0.95
parameter	k = 0.10110	α = 0.5511	k1 = 4.28828	k1 = 0.368839
	M(0) = 10.10576	β = 1.7346	k2 = 0.07994	k2 = 0.079620
		M(0) = 11.4773	g = 0.33345	tb = 1.040435
			M(0) = 13.26376	M(0) = 11.915719
lower CI	k = 0.05897	α = -0.3318	k1 = -25.26500	k1 = 0.085717
	M(0) = 8.63988	β = -4.4168	k2 = 0.04159	k2 = 0.043485
		M(0) = 8.4290	g = -0.43621	tb = 0.006781
			M(0) = -3.00006	M(0) = 9.859875
upper CI	k = 0.143	α = 1.434	k1 = 33.842	k1 = 0.652
	M(0) = 11.572	β = 7.886	k2 = 0.118	k2 = 0.116

		M(0) = 14.526	g = 1.103	tb = 2.074
			M(0) = 29.528	M(0) = 13.972
t-test	p(k): 0.00266	-	p(k1): 0.3973	p(k1): 0.041849
			p(k2): 0.0132	p(k2): 0.011438

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;
 HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant (ln(2)/DT50)
 α = $3.4735 \cdot N^{-0.8629}$
 β = $DT50 / (2^{(1/\alpha)} - 1)$
 N = $DT90 / DT50 - 3.32$
 DT₅₀ = estimated from the data
 DT₉₀ = estimated from the data
 k1 = rate constant for the fast degradation phase (ln(2)/DT50f)
 k2 = rate constant for the slow degradation phase (ln(2)/DT50s)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

Wheat Green Mass

For wheat samples all of the models achieved the critical values < 15 for χ^2 -error and for the determination coefficient of $r^2 > 0.85$. The FOMC and DFOP models showed either negative confidence intervals or were not statistically significant. The HS and the SFO model showed no negative confidence intervals and were statistically significant. For the SFO model the calculated χ^2 -error was 5.77 and the calculated r^2 was 0.98. The results of the calculation for the SFO model showed a DT50 value of 4.62 days and a DT90 value of 15.35 days, respectively.

Table A 2-59: Results and parameters of the kinetic degradation of zoxamide in/on wheat green mass (Trial S19-23773-01)

Model	SFO	FOMC	DFOP	HS
DT₅₀ [days]	4.62	4.38	4.25	4.62
DT₉₀ [days]	15.35	16.71	16.04	15.39
CHI²-err [%]	5.77	6.05	6.22	6.86
r²	0.98	0.98	0.99	0.98
parameter	k = 0.15005	α = 6.0561	k1 = 0.98740	k1 = 0.15005
	M(0) = 9.46630	β = 36.1182	k2 = 0.13622	k2 = 0.09333
		M(0) = 9.6010	g = 0.11052	tb = 15.26760
			M(0) = 9.81765	M(0) = 9.46630
lower CI	k = 0.12470	α = -22.6811	k1 = -3.05244	k1 = 0.11760
	M(0) = 8.82664	β = -154.1444	k2 = 0.07967	k2 = 0.04410
		M(0) = 8.6810	g = -0.22503	tb = 3.21631
			M(0) = 8.76221	M(0) = 8.61498
upper CI	k = 0.175	α = 34.79	k1 = 5.027	k1 = 0.182
	M(0) = 10.106	β = 226.38	k2 = 0.193	k2 = 0.143
		M(0) = 10.52	g = 0.446	tb = 27.319
			M(0) = 10.873	M(0) = 10.318
t-test	p(k): 4.17e ⁻⁰⁵	-	p(k1): 0.33233	p(k1): 0.001418
			p(k2): 0.00900	p(k2): 0.016949

SFO = Single first order kinetic;
 FOMC = First order multi compartment kinetic;
 DFOP = Double first order kinetic;

HS = Hockey stick kinetic
 M(0) = initial concentration
 CI = confidence interval
 t = time after time of initial concentration
 k = rate constant ($\ln(2)/DT50$)
 $\alpha = 3.4735 \cdot N^{-0.8629}$
 $\beta = DT50 / (2^{(1/\alpha)} - 1)$
 N = $DT90/DT50 - 3.32$
 DT50 = estimated from the data
 DT90 = estimated from the data
 k1 = rate constant for the fast degradation phase ($\ln(2)/DT50f$)
 k2 = rate constant for the slow degradation phase ($\ln(2)/DT50s$)
 tb = break point time estimated from the data rate
 g = 1-F
 F = estimated residual fraction at the time when the fast degradation phase changes to the slow degradation phase

The following figures show residues of zoxamide.

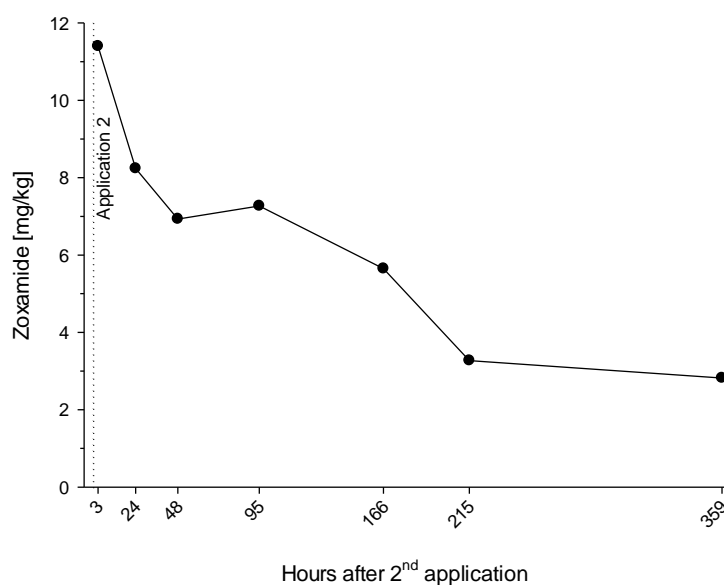


Figure A 13: Residues of zoxamide in sugar beet leaves over time (trial 01)

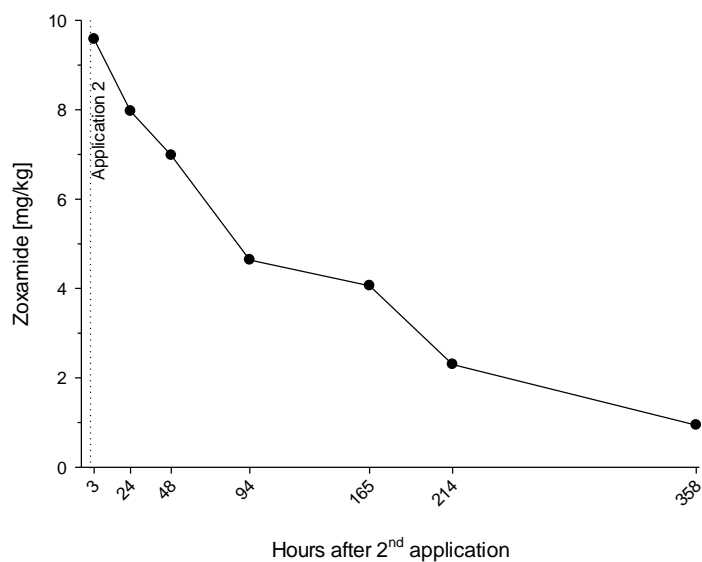


Figure A 14: Residues of zoxamide in wheat green mass over time (trial -01)

Conclusion

The residue decline of zoxamide on sugar beet leaves (as surrogate dicotyledonae plant) and wheat green mass (as surrogate monocotyledonae plant) has been studied in the field under representative growing conditions for Southern Europe (Italy) in the field. In sugar beet leaves (as surrogate dicotyledonae plant) and in wheat green mass (as surrogate monocotyledonae plant), the residues and degradation kinetics of the active ingredient were investigated after two applications of Zoxium 240 SC (240 g/L zoxamide, SC) at application rates for zoxamide of 180 g a.i./ha with an interval of 7 days (BBCH 17-21 for sugar beet and wheat).

For the degradation of zoxamide in sugar beet leaves, the single first order (SFO) degradation was calculated at 6.86 days and the DT90 was calculated at 22.78 days. For the degradation of zoxamide in wheat green mass, the single first order (SFO) DT50 was calculated at 4.62 days and the DT90 was calculated at 15.35 days.

(Appeltauer A. 2020)

A 2.11 Study 11 – Overall DegT₅₀ of zoxamide on/in plants

Substance specific DT₅₀ 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/in plants has been performed by Klein & Mendel-Kreusel (2020), summarised in the following.

Comments of zRMS:	<p>The study report was evaluated and accepted. Based on residual studies all relevant data could be used in kinetics assessment of zoxamide residues.</p> <p>The kinetics analysis was performed in accordance with FOCUS guidance and relevant mathematical tool was used KinGUII. Based on studies conducted in Northern and South Europe the following DT₅₀ were calculated:</p> <ul style="list-style-type: none"> • 4.2 d (geometric mean DT₅₀ value for n=16); indoor and Southern European field condition and in leafy (dicotyledonous) plants; • 3.6 d (geometric mean DT₅₀ value for n=16); Southern and Northern European field conditions and leafy (dicotyledonous) and grass-like (monocotyledonous) plants; • 3.9 d (geometric mean DT₅₀ value for n = 32); Southern and Northern European field conditions and leafy (dicotyledonous) and grass-like (monocotyledonous) plants. <p>The DT₅₀ = 3.9 d was accepted for PEC_{sw} assessment in Step 3 and Step 4.</p>
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Reference:	KCP 9.2.5/06
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, 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 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 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 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 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: In sugar beet leaves (as surrogate leafy/dicotyledonae plant) and in 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 DT₅₀ values and DT₉₀ values.

Table A 2-60: 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
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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

*Appeltauer (2020a)

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 in representative plants grown under Southern European (Bulgarian and Spanish) field conditions: In sugar beet green mass (as surrogate leafy/dicotyledonae plant) and in 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 summarized, which were used as input for the computer software KinGUII (version 2.2012) to calculate DT₅₀ values and DT₉₀ values.

Table A 2-61: 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

*Appeltauer (2020b)

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 in representative plants grown under Northern European field conditions (The Netherlands): In sugar beet leaves (as surrogate leafy/dicotyledonae plant) and in 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 in/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 DT₅₀ values and DT₉₀ values.

Table A 2-62: 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

*Appeltauer (2020c)

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 in representative plants grown under Southern European field conditions (Italy) were investigated: In sugar beet leaves (as surrogate leafy/dicotyledonae plant) and in 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.i./ha with an interval of 7 days (BBCH 17-21 of plants). The experimental result taken from Appeltauer (2020d), the concentration of zoxamide in/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 DT₅₀ and DT₉₀ values.

Table A 2-63: 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

*Appeltauer (2020d)

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 DT₅₀ values for zoxamide were calculated. The calculation of the DT₅₀ values and DT₉₀ 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 (X²).
2. Additionally, the coefficient of determination (r²) 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 r².

The best kinetic models/fits are indicated in **bold**.

Results and discussions

Table A 2-64: Results of calculation for all kinetic models for zoxamide in/on sugar beet leaves and wheat green mass; Northern EU, study S16-05375 performed by Appeltauer (2020a)

	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

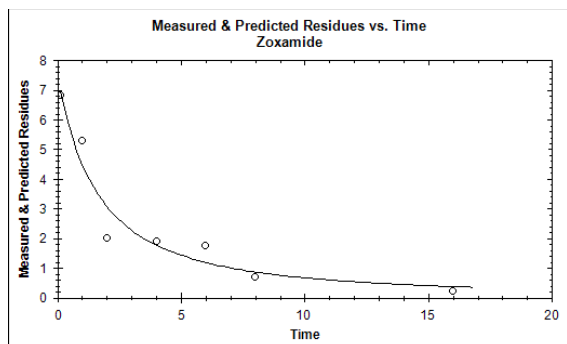
For both crop varieties, the X^2 -values for the best fit models are mainly $< 15\%$. Only for sugar beet leaves, the first trial yields a X^2 -value greater than 15% . Here, the best fit kinetic is FOMC with an error of 18.02% . However, the visual fit is acceptable and the coefficient of determination (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 and 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% .

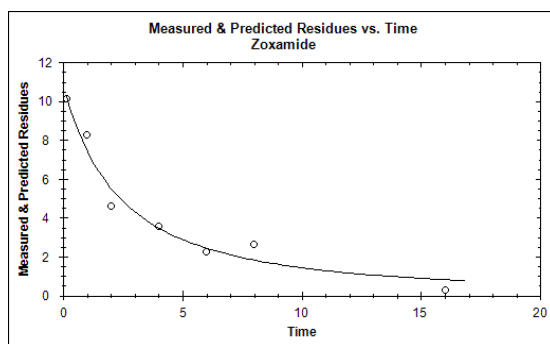
For wheat green mass trial 2 and trial 3 minimum X^2 -values were found for SFO kinetics. The choice of kinetics was confirmed by the good visual fits (see following figure, demonstrating good visual fits for the best fit kinetics).

S16-05375-01

sugar beet leaves (FOMC)

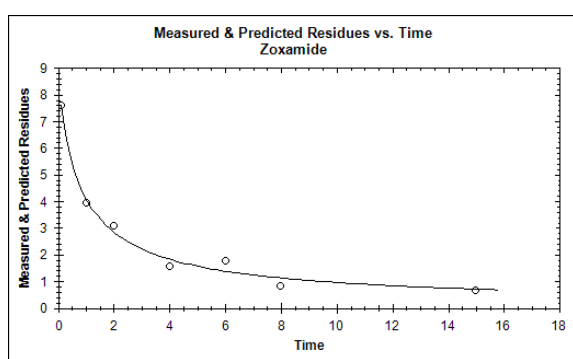


wheat green mass (FOMC)

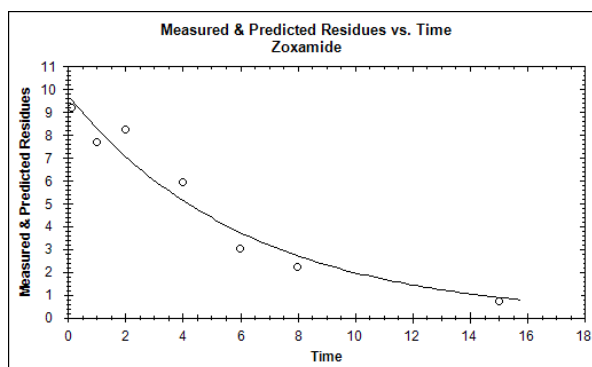


S16-05375-02

sugar beet leaves (FOMC)

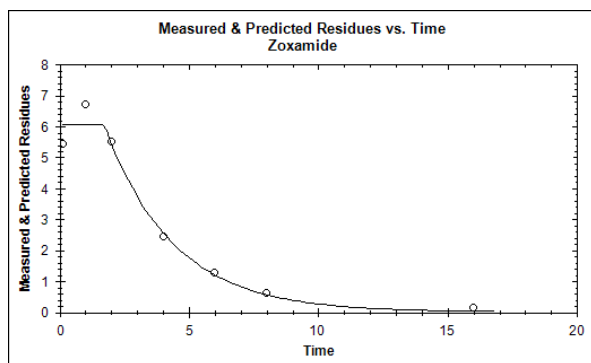


wheat green mass (SFO)



S16-05375-03

sugar beet leaves (HS)



wheat green mass (SFO)

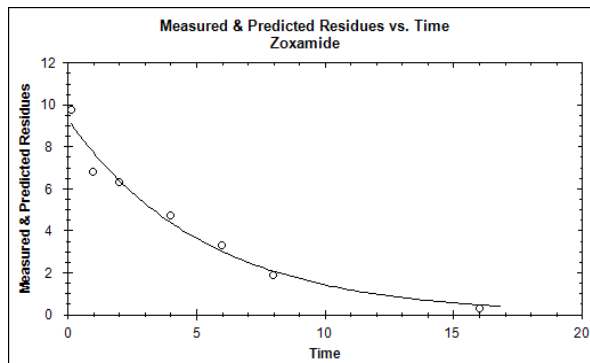


Figure A 15: Plot with the residue decline data of zoxamide using the best fit kinetics for sugar beet leaves and wheat green mass -Northern EU, Study S16-05375 performed by Appeltauer (2020a)

Table A 2-65: Results of calculation for all kinetic models for zoxamide in/on sugar beet leaves and wheat green mass; Southern EU study S16-05376 performed by Appeltauer (2020b)

	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%.

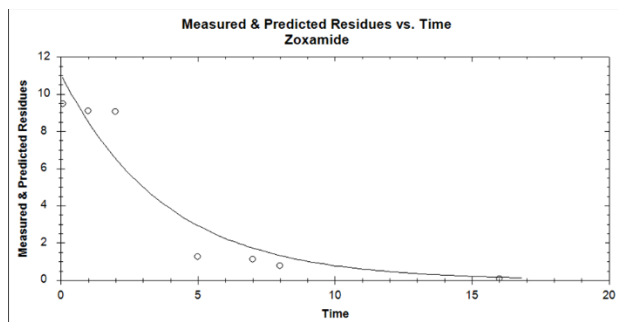
In general, the coefficients of determination (r^2) for all chosen best fit kinetics are greater than or equal to 0.9. As a result, the correspondence between the model predictions and the observed data is good for all data sets. Hence, the calculated DT_{50} values are reliable.

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.

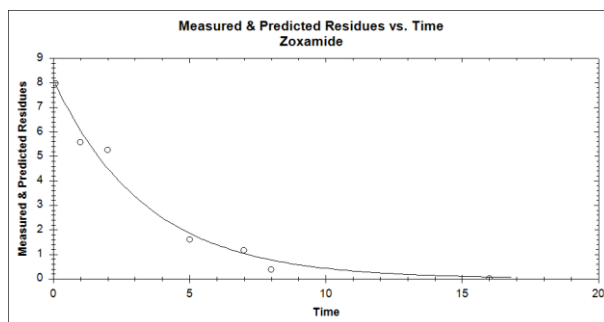
The choice of kinetics was confirmed by the good visual fits (see next figure, demonstrating good visual fits for the best fit kinetics).

S16-05376-01

sugar beet leaves (SFO)

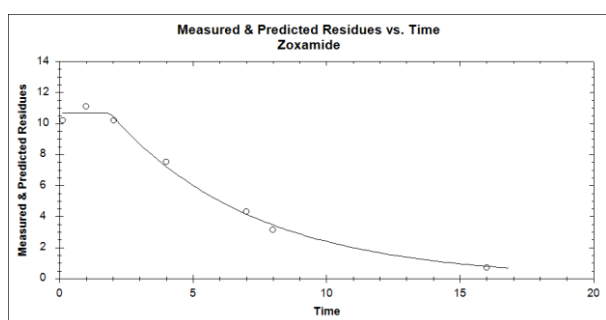


wheat green mass (SFO)

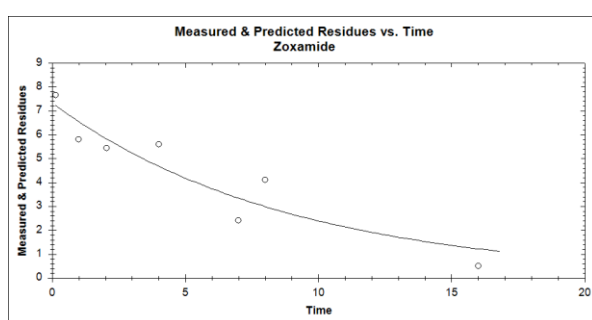


S16-05376-02

sugar beet leaves (HS)

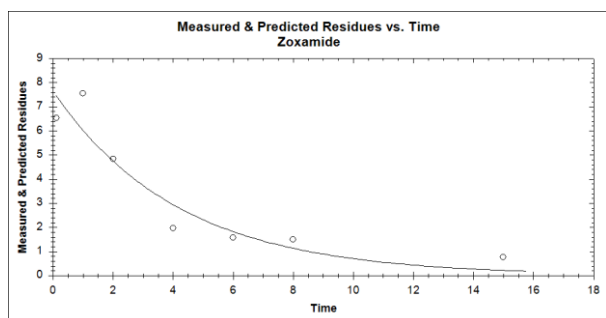


wheat green mass (SFO)



S16-05376-03

sugar beet leaves (SFO)



wheat green mass (DFOP)

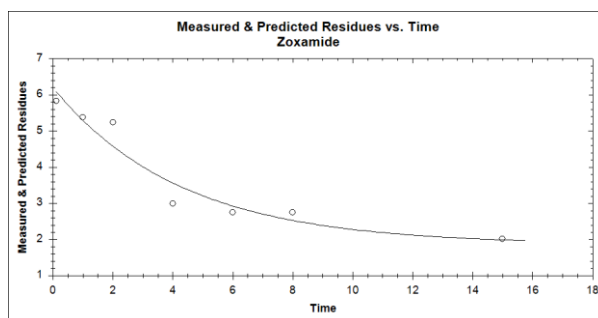


Figure A 16: Plot with the residue decline data of zoxamide using the best fit kinetics for sugar beet leaves and wheat green mass -Southern EU, Study S16-05376 performed by Appeltauer (2020b)

Table A 2-66: Results of calculation for all kinetic models for zoxamide in/on sugar beet leaves and wheat green mass; Northern EU, study S19-01450 performed by Appeltauer (2020c)

	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

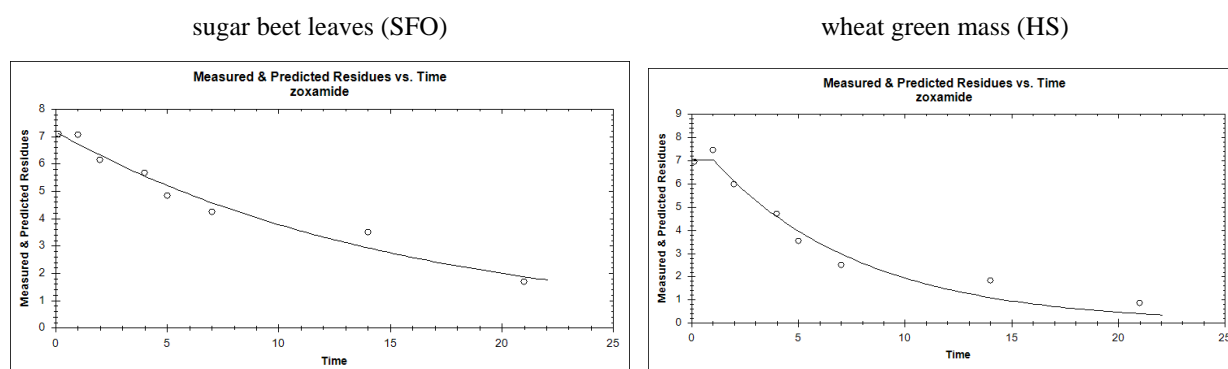


Figure A 17: Plot with the residue decline data of zoxamide using the best fit kinetics for sugar beet leaves and wheat green mass -Northern EU, study S19-01450 performed by Appeltauer (2020c)

Table A 2-67: Zoxamide residues on sugar beet leaves and wheat green mass, study S19-23773; Southern EU, Study S19-23773 performed by Appeltauer (2020d)

	Crop	Field trial no.	Kinetics	X^2 [%]	r^2	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 χ^2 and r^2 for DFOP and HS. The selection also represent the worst case

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 smallest X^2 -values are obtained for DFOP and HS, namely 8.76%. As both, X^2 -values and coefficient of determination (r^2). HS is selected as best fit kinetic as it represents the worst case.

For wheat green mass, X^2 -values are for all kinetic models in a similar range. The smallest X^2 -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

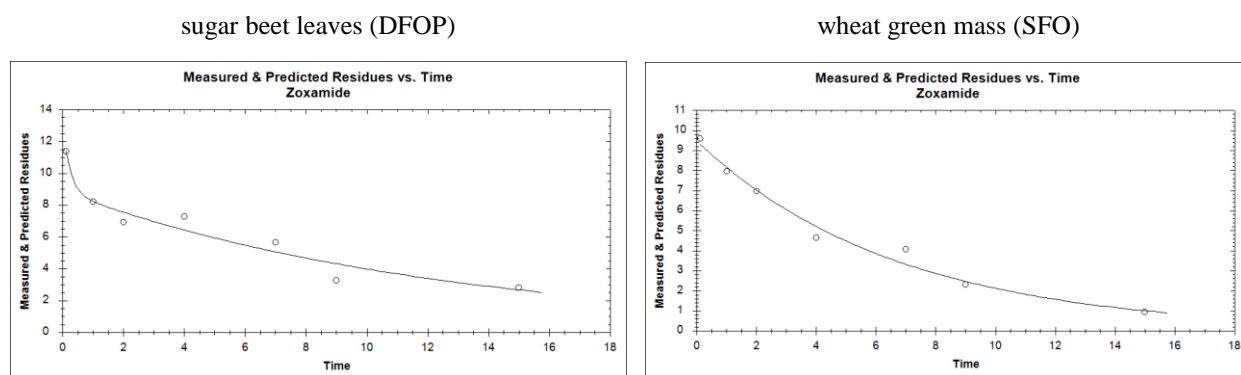


Figure A 18: Plot with the residue decline data of zoxamide using the best fit kinetics for sugar beet leaves and wheat green mass -Northern EU, Study S19-23773 performed by Appeltauer (2020d)

In the kinetic evaluation report the fitting results are presented in more detail.

The overall results are summarised in the following table.

Table A 2-68: Residue dissipation of zoxamide on/in 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-life (n = 8) Southern EU ± SD				4.1 ± 1.5
Geometric mean half-life (n = 15) ± SD				3.6 ± 2.4

In total, 8 trials were available for each, Northern EU and Southern EU. 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). These studies describe the residue of zoxamide on/in open headed salad variations (as surrogate plants for leafy crops) under indoor and outdoor (Southern European) conditions:

1. Salad under open field southern EU: Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC
2. Salad under indoor conditions: Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC

In order to calculate the overall DT₅₀ of all experiments these studies were included. As presented in the next table, the overall DT₅₀ including all studies (n = 32) is 3.9 days.

Table A 2-69: Overall geometric mean for the residue dissipation of zoxamide under southern and northern EU field and indoor conditions

	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					
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

	RA 12 058BPL IT 03	Lettuce Trocadero (4)	HS	6.58	0.9888	1.79
		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

* Luciani G.P. 2012, report no. AGRI 013/12 GLP DEC

** Luciani G.P. 2012, report no. AGRI 014/12 GLP DEC

In summary, DT₅₀ values (n=16) for zoxamide on/in 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/in leafy (dicotyledonae) and grass-like (monocotyledonae) plants.

The geometric mean DT₅₀ value (n=16) for zoxamide on/in 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/in leafy (dicotyledonous) plants.

The overall geometric mean DT₅₀ value (n=32) for zoxamide on/in 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 and 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.

(Klein J. & Mendel-Kreusel R. 2020)

Appendix 3 formation provided by the applicant (e.g. detailed modelling data)

Appendix 3.1 - Selected output files

Appendix 3.1 - Selected output files

PEARL –Output file (zoxamide, Châteaudun, potato)

```

* PEARL REPORT: Header
* Results from the PEARL model (c) Alterra, PBL and RIVM
* PEARL kernel version : 3.1.2
* SWAP kernel version : swap3234
* PEARL created on : 18-Feb-2011
*
* PEARL was called from : FOCUSPEARL, version 4.4.4
* Working directory : C:\FOCUSPEARL_4_4_4\PearlDB
* Run ID : 145
* Input file generated on : 09-10-2020
* -----
*
* Location : CHATEAUDUN
* Meteo station : CHAT-M
* Soil type : CHAT-S_Soil
* Crop calendar : CHAT-SPOTATOES
* Substance : ZOX
* Application scheme : Potato_ZOX
* Deposition scheme : No
* Irrigation scheme : FOCUS
*
* End of PEARL REPORT: Header

* PEARL REPORT: Leaching
* Start date : 01-Jan-1901
* End date : 31-Dec-1926
* Target depth : 1.00 m
* Annual application to the soil surface at 13-May; dosage = 0.0594 kg.ha-1
* Annual application to the soil surface at 20-May; dosage = 0.0594 kg.ha-1
* Annual application to the soil surface at 27-May; dosage = 0.0594 kg.ha-1

* Leaching summary for compound ZOX
* Molar mass (g.mol-1) : 336.6
* Saturated vapour pressure (Pa) : 0.130E-04; measured at (C) 25.0
* Solubility in water (mg.L-1) : 0.680 ; measured at (C) 20.0
* Half-life (d) : 5.5; measured at (C) 20.0
* Kom (coef. for sorption on organic matter) (L.kg-1) : 684.0
* KF (overall sorption coefficient of the target layer) (L.kg-1) : 9.03
* Freundlich exponent (-) : 0.97
* -----
* Period From To Water percolated Substance leached
Average substance below target depth (mm) below target depth (kg/ha)
* number concentration in water at
target depth (ug/L)
* -----
1 01-Jan-1907 31-Dec-1907 292.079 0.0000000
0.000
2 01-Jan-1908 31-Dec-1908 85.789 0.0000000
0.000
3 01-Jan-1909 31-Dec-1909 251.479 0.0000000
0.000
4 01-Jan-1910 31-Dec-1910 252.401 0.0000000
0.000
5 01-Jan-1911 31-Dec-1911 368.808 0.0000000
0.000
6 01-Jan-1912 31-Dec-1912 229.438 0.0000000
0.000
7 01-Jan-1913 31-Dec-1913 275.464 0.0000000
0.000
8 01-Jan-1914 31-Dec-1914 315.212 0.0000000
0.000
9 01-Jan-1915 31-Dec-1915 196.954 0.0000000
0.000

```

10	01-Jan-1916	31-Dec-1916	364.726	0.0000000
0.000				
11	01-Jan-1917	31-Dec-1917	146.625	0.0000000
0.000				
12	01-Jan-1918	31-Dec-1918	181.183	0.0000000
0.000				
13	01-Jan-1919	31-Dec-1919	250.990	0.0000000
0.000				
14	01-Jan-1920	31-Dec-1920	255.761	0.0000000
0.000				
15	01-Jan-1921	31-Dec-1921	114.380	0.0000000
0.000				
16	01-Jan-1922	31-Dec-1922	62.419	0.0000000
0.000				
17	01-Jan-1923	31-Dec-1923	119.498	0.0000000
0.000				
18	01-Jan-1924	31-Dec-1924	170.094	0.0000000
0.000				
19	01-Jan-1925	31-Dec-1925	121.070	0.0000000
0.000				
20	01-Jan-1926	31-Dec-1926	149.874	0.0000000
0.000				

* The average concentration of ZOX closest to the 80th percentile is 0.000000 ug/L

* Leaching summary for compound ZOX_1

* Molar mass (g.mol-1) : 302.1
 * Saturated vapour pressure (Pa) : 0.00 ; measured at (C) 20.0
 * Solubility in water (mg.L-1) : 0.100E+04; measured at (C) 20.0
 * Half-life (d) : 5.2; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 344.0
 * KF (overall sorption coefficient of the target layer) (L.kg-1) : 4.54
 * Freundlich exponent (-) : 0.90

 * Period From To Water percolated Substance leached
 Average substance below target depth (mm) below target depth (kg/ha)
 * number concentration in water at
 target depth (ug/L)
 * -----

1	01-Jan-1907	31-Dec-1907	292.079	0.0000000
0.000				
2	01-Jan-1908	31-Dec-1908	85.789	0.0000000
0.000				
3	01-Jan-1909	31-Dec-1909	251.479	0.0000000
0.000				
4	01-Jan-1910	31-Dec-1910	252.401	0.0000000
0.000				
5	01-Jan-1911	31-Dec-1911	368.808	0.0000000
0.000				
6	01-Jan-1912	31-Dec-1912	229.438	0.0000000
0.000				
7	01-Jan-1913	31-Dec-1913	275.464	0.0000000
0.000				
8	01-Jan-1914	31-Dec-1914	315.212	0.0000000
0.000				
9	01-Jan-1915	31-Dec-1915	196.954	0.0000000
0.000				
10	01-Jan-1916	31-Dec-1916	364.726	0.0000000
0.000				
11	01-Jan-1917	31-Dec-1917	146.625	0.0000000
0.000				
12	01-Jan-1918	31-Dec-1918	181.183	0.0000000
0.000				
13	01-Jan-1919	31-Dec-1919	250.990	0.0000000
0.000				
14	01-Jan-1920	31-Dec-1920	255.761	0.0000000
0.000				
15	01-Jan-1921	31-Dec-1921	114.380	0.0000000
0.000				
16	01-Jan-1922	31-Dec-1922	62.419	0.0000000
0.000				
17	01-Jan-1923	31-Dec-1923	119.498	0.0000000
0.000				
18	01-Jan-1924	31-Dec-1924	170.094	0.0000000
0.000				
19	01-Jan-1925	31-Dec-1925	121.070	0.0000000
0.000				
20	01-Jan-1926	31-Dec-1926	149.874	0.0000000

0.000

* The average concentration of ZOX_1 closest to the 80th percentile is 0.000000 ug/L

* Leaching summary for compound ZOX_2

* Molar mass (g.mol-1) : 205.0
* Saturated vapour pressure (Pa) : 0.00 ; measured at (C) 20.0
* Solubility in water (mg.L-1) : 0.100E+04; measured at (C) 20.0
* Half-life (d) : 6.8; measured at (C) 20.0
* Kom (coef. for sorption on organic matter) (L.kg-1) : 52.5
* KF (overall sorption coefficient of the target layer) (L.kg-1) : 0.693
* Freundlich exponent (-) : 0.81

* Period	From	To	Water percolated	Substance leached
Average substance				
* number			below target depth (mm)	below target depth (kg/ha)
concentration in water				
* target depth (ug/L)				at
* -----				
1	01-Jan-1907	31-Dec-1907	292.079	0.0000000
0.000				
2	01-Jan-1908	31-Dec-1908	85.789	0.0000000
0.000				
3	01-Jan-1909	31-Dec-1909	251.479	0.0000000
0.000				
4	01-Jan-1910	31-Dec-1910	252.401	0.0000000
0.000				
5	01-Jan-1911	31-Dec-1911	368.808	0.0000000
0.000				
6	01-Jan-1912	31-Dec-1912	229.438	0.0000000
0.000				
7	01-Jan-1913	31-Dec-1913	275.464	0.0000000
0.000				
8	01-Jan-1914	31-Dec-1914	315.212	0.0000000
0.000				
9	01-Jan-1915	31-Dec-1915	196.954	0.0000000
0.000				
10	01-Jan-1916	31-Dec-1916	364.726	0.0000000
0.000				
11	01-Jan-1917	31-Dec-1917	146.625	0.0000000
0.000				
12	01-Jan-1918	31-Dec-1918	181.183	0.0000000
0.000				
13	01-Jan-1919	31-Dec-1919	250.990	0.0000000
0.000				
14	01-Jan-1920	31-Dec-1920	255.761	0.0000000
0.000				
15	01-Jan-1921	31-Dec-1921	114.380	0.0000000
0.000				
16	01-Jan-1922	31-Dec-1922	62.419	0.0000000
0.000				
17	01-Jan-1923	31-Dec-1923	119.498	0.0000000
0.000				
18	01-Jan-1924	31-Dec-1924	170.094	0.0000000
0.000				
19	01-Jan-1925	31-Dec-1925	121.070	0.0000000
0.000				
20	01-Jan-1926	31-Dec-1926	149.874	0.0000000
0.000				

* The average concentration of ZOX_2 closest to the 80th percentile is 0.000000 ug/L

* Leaching summary for compound ZOX4

* Molar mass (g.mol-1) : 235.0
* Saturated vapour pressure (Pa) : 0.00 ; measured at (C) 20.0
* Solubility in water (mg.L-1) : 0.100E+04; measured at (C) 20.0
* Half-life (d) : 7.5; measured at (C) 20.0
* Kom (coef. for sorption on organic matter) (L.kg-1) : 1.6
* KF (overall sorption coefficient of the target layer) (L.kg-1) : 0.211E-01
* Freundlich exponent (-) : 1.00

* Period	From	To	Water percolated	Substance leached
Average substance				
* number			below target depth (mm)	below target depth (kg/ha)
concentration in water				
* target depth (ug/L)				at
* -----				

1	01-Jan-1907	31-Dec-1907	292.079	0.0000319
0.011				
2	01-Jan-1908	31-Dec-1908	85.789	0.0000016
0.002				
3	01-Jan-1909	31-Dec-1909	251.479	0.0000123
0.005				
4	01-Jan-1910	31-Dec-1910	252.401	0.0000302
0.012				
5	01-Jan-1911	31-Dec-1911	368.808	0.0000461
0.012				
6	01-Jan-1912	31-Dec-1912	229.438	0.0000200
0.009				
7	01-Jan-1913	31-Dec-1913	275.464	0.0000352
0.013				
8	01-Jan-1914	31-Dec-1914	315.212	0.0000563
0.018				
9	01-Jan-1915	31-Dec-1915	196.954	0.0000077
0.004				
10	01-Jan-1916	31-Dec-1916	364.726	0.0000831
0.023				
11	01-Jan-1917	31-Dec-1917	146.625	0.0000129
0.009				
12	01-Jan-1918	31-Dec-1918	181.183	0.0000079
0.004				
13	01-Jan-1919	31-Dec-1919	250.990	0.0000430
0.017				
14	01-Jan-1920	31-Dec-1920	255.761	0.0000308
0.012				
15	01-Jan-1921	31-Dec-1921	114.380	0.0000051
0.004				
16	01-Jan-1922	31-Dec-1922	62.419	0.0000007
0.001				
17	01-Jan-1923	31-Dec-1923	119.498	0.0000036
0.003				
18	01-Jan-1924	31-Dec-1924	170.094	0.0000118
0.007				
19	01-Jan-1925	31-Dec-1925	121.070	0.0000099
0.008				
20	01-Jan-1926	31-Dec-1926	149.874	0.0000180
0.012				

* The average concentration of ZOX4 closest to the 80th percentile is 0.012640 ug/L

* Leaching summary for compound ZOX_3

* Molar mass (g.mol⁻¹) : 332.1
 * Saturated vapour pressure (Pa) : 0.00 ; measured at (C) 20.0
 * Solubility in water (mg.L⁻¹) : 0.100E+04; measured at (C) 20.0
 * Half-life (d) : 10.8; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg⁻¹) : 39.0
 * KF (overall sorption coefficient of the target layer) (L.kg⁻¹) : 0.515
 * Freundlich exponent (-) : 0.89

* Period	From	To	Water percolated	Substance leached
Average substance				
* number			below target depth (mm)	below target depth (kg/ha)
concentration in water				
				at
target depth (ug/L)				
1	01-Jan-1907	31-Dec-1907	292.079	0.0000000
0.000				
2	01-Jan-1908	31-Dec-1908	85.789	0.0000000
0.000				
3	01-Jan-1909	31-Dec-1909	251.479	0.0000000
0.000				
4	01-Jan-1910	31-Dec-1910	252.401	0.0000000
0.000				
5	01-Jan-1911	31-Dec-1911	368.808	0.0000000
0.000				
6	01-Jan-1912	31-Dec-1912	229.438	0.0000000
0.000				
7	01-Jan-1913	31-Dec-1913	275.464	0.0000000
0.000				
8	01-Jan-1914	31-Dec-1914	315.212	0.0000000
0.000				
9	01-Jan-1915	31-Dec-1915	196.954	0.0000000
0.000				
10	01-Jan-1916	31-Dec-1916	364.726	0.0000000
0.000				

11	01-Jan-1917	31-Dec-1917	146.625	0.0000000
0.000				
12	01-Jan-1918	31-Dec-1918	181.183	0.0000000
0.000				
13	01-Jan-1919	31-Dec-1919	250.990	0.0000000
0.000				
14	01-Jan-1920	31-Dec-1920	255.761	0.0000000
0.000				
15	01-Jan-1921	31-Dec-1921	114.380	0.0000000
0.000				
16	01-Jan-1922	31-Dec-1922	62.419	0.0000000
0.000				
17	01-Jan-1923	31-Dec-1923	119.498	0.0000000
0.000				
18	01-Jan-1924	31-Dec-1924	170.094	0.0000000
0.000				
19	01-Jan-1925	31-Dec-1925	121.070	0.0000000
0.000				
20	01-Jan-1926	31-Dec-1926	149.874	0.0000000
0.000				

* The average concentration of ZOX_3 closest to the 80th percentile is 0.000000 ug/L

* End of PEARL REPORT: Leaching

PELMO–Output file (zoxamide, Châteaudun, potato)

*** FOCUSPELMO 5. 5. 3 *** (PELMO 4.01)
Ver 3 Chfteaudun, potatoes
(C) Zoxamide potatoes
Ver 3 Chfteaudun scenario (48.05 N, 1.38 E)) Year:01

Results for ACTIVE SUBSTANCE (Zoxamide) in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00E+00	274.900	0.000
2	0.00E+00	126.900	0.000
3	0.00E+00	254.900	0.000
4	0.00E+00	282.700	0.000
5	0.00E+00	351.000	0.000
6	0.00E+00	246.700	0.000
7	0.00E+00	307.800	0.000
8	0.00E+00	282.000	0.000
9	0.00E+00	162.300	0.000
10	0.00E+00	389.800	0.000
11	0.00E+00	146.800	0.000
12	0.00E+00	193.700	0.000
13	0.00E+00	267.100	0.000
14	0.00E+00	268.400	0.000
15	0.00E+00	119.700	0.000
16	0.00E+00	80.9800	0.000
17	0.00E+00	88.7100	0.000
18	0.00E+00	164.300	0.000
19	0.00E+00	136.800	0.000
20	0.00E+00	152.300	0.000

Total	0.00E+00	4297.79	0.000
80 Perc. (4/5)	0.00E+00	633.700	0.000

Results for METABOLITE A1 (RH-127450) in the percolate at 1 m soil depth

Period	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00E+00	274.900	0.000
2	0.00E+00	126.900	0.000
3	0.00E+00	254.900	0.000
4	0.00E+00	282.700	0.000
5	0.00E+00	351.000	0.000
6	0.00E+00	246.700	0.000
7	0.00E+00	307.800	0.000
8	0.00E+00	282.000	0.000
9	0.00E+00	162.300	0.000
10	0.00E+00	389.800	0.000
11	6.21E-22	146.800	0.000
12	0.00E+00	193.700	0.000
13	0.00E+00	267.100	0.000
14	0.00E+00	268.400	0.000
15	0.00E+00	119.700	0.000
16	0.00E+00	80.9800	0.000
17	0.00E+00	88.7100	0.000
18	0.00E+00	164.300	0.000
19	0.00E+00	136.800	0.000
20	0.00E+00	152.300	0.000

Total	6.21E-22	4297.79	0.000
80 Perc. (3/4)	0.00E+00	537.600	0.000

Results for METABOLITE B1 (RH-24549) in the percolate at 1 m soil depth

Period	Metab.B1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	4.06E-17	274.900	0.000
2	3.65E-17	126.900	0.000
3	7.88E-16	254.900	0.000
4	4.22E-15	282.700	0.000
5	1.34E-14	351.000	0.000
6	1.15E-14	246.700	0.000
7	2.73E-15	307.800	0.000
8	8.82E-16	282.000	0.000
9	1.04E-14	162.300	0.000
10	1.36E-15	389.800	0.000
11	4.43E-14	146.800	0.000
12	-1.58E-15	193.700	0.000
13	-2.21E-15	267.100	0.000
14	5.57E-14	268.400	0.000

15	-3.23E-15	119.700	0.000
16	-2.19E-15	80.9800	0.000
17	-1.22E-15	88.7100	0.000
18	-1.38E-15	164.300	0.000
19	-5.98E-16	136.800	0.000
20	-3.29E-16	152.300	0.000

Total	1.33E-13	4297.79	0.000
80 Perc. (6/5)	2.49E-14	597.700	0.000

Results for METABOLITE C1 (RH-163353) in the percolate at 1 m soil depth

Period	Metab.C1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)

1	4.88E-08	274.900	0.000
2	2.60E-08	126.900	0.000
3	3.06E-07	254.900	0.000
4	9.78E-07	282.700	0.000
5	2.30E-06	351.000	0.000
6	1.80E-06	246.700	0.000
7	9.72E-07	307.800	0.000
8	4.69E-07	282.000	0.000
9	1.60E-06	162.300	0.000
10	7.03E-07	389.800	0.000
11	3.58E-06	146.800	0.000
12	5.96E-07	193.700	0.000
13	1.03E-07	267.100	0.000
14	5.44E-06	268.400	0.000
15	1.65E-07	119.700	0.000
16	-8.88E-08	80.9800	0.000
17	-2.66E-08	88.7100	0.000
18	-2.91E-08	164.300	0.000
19	5.41E-09	136.800	0.000
20	3.32E-08	152.300	0.000

Total	1.90E-05	4297.79	0.000
80 Perc. (6/5)	4.10E-06	597.700	0.000

Results for METABOLITE B2 (RH-141455) in the percolate at 1 m soil depth

Period	Metab.B2 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)

1	0.0087080	274.900	0.003
2	0.0037710	126.900	0.003
3	0.0085800	254.900	0.003
4	0.0251100	282.700	0.009
5	0.0391900	351.000	0.011
6	0.0166600	246.700	0.007
7	0.0308200	307.800	0.010
8	0.0277900	282.000	0.010
9	0.0065160	162.300	0.004
10	0.0410900	389.800	0.011
11	0.0143800	146.800	0.010
12	0.0022380	193.700	0.001
13	0.0304000	267.100	0.011
14	0.0394000	268.400	0.015
15	0.0036780	119.700	0.003
16	5.49E-05	80.9800	0.000
17	9.87E-04	88.7100	0.001
18	0.0027850	164.300	0.002
19	0.0041520	136.800	0.003
20	0.0093570	152.300	0.006

Total	0.3156669	4297.79	0.007
80 Perc. (10/7)	0.0719100	697.600	0.010

Results for ACTIVE SUBSTANCE (Zoxamide) in the percolate at the bottom of the simulated soil core

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)

1	0.00E+00	274.900	0.000
2	0.00E+00	126.900	0.000
3	0.00E+00	254.900	0.000
4	0.00E+00	282.700	0.000
5	0.00E+00	351.000	0.000
6	0.00E+00	246.700	0.000
7	0.00E+00	307.800	0.000
8	0.00E+00	282.000	0.000
9	0.00E+00	162.300	0.000
10	0.00E+00	389.800	0.000
11	0.00E+00	146.800	0.000
12	0.00E+00	193.700	0.000

13	0.00E+00	267.100	0.000
14	0.00E+00	268.400	0.000
15	0.00E+00	119.700	0.000
16	0.00E+00	80.9800	0.000
17	0.00E+00	88.7100	0.000
18	0.00E+00	164.300	0.000
19	0.00E+00	136.800	0.000
20	0.00E+00	152.300	0.000

Total	0.00E+00	4297.79	0.000
80 Perc. (4/5)	0.00E+00	633.700	0.000

Results for METABOLITE A1 (RH-127450) in the percolate at the bottom of the simulated soil core

Period	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00E+00	274.900	0.000
2	0.00E+00	126.900	0.000
3	0.00E+00	254.900	0.000
4	0.00E+00	282.700	0.000
5	0.00E+00	351.000	0.000
6	0.00E+00	246.700	0.000
7	0.00E+00	307.800	0.000
8	0.00E+00	282.000	0.000
9	0.00E+00	162.300	0.000
10	0.00E+00	389.800	0.000
11	0.00E+00	146.800	0.000
12	0.00E+00	193.700	0.000
13	0.00E+00	267.100	0.000
14	0.00E+00	268.400	0.000
15	0.00E+00	119.700	0.000
16	0.00E+00	80.9800	0.000
17	0.00E+00	88.7100	0.000
18	0.00E+00	164.300	0.000
19	0.00E+00	136.800	0.000
20	0.00E+00	152.300	0.000

Total	0.00E+00	4297.79	0.000
80 Perc. (4/5)	0.00E+00	633.700	0.000

Results for METABOLITE B1 (RH-24549) in the percolate at the bottom of the simulated soil core

Period	Metab.B1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00E+00	274.900	0.000
2	0.00E+00	126.900	0.000
3	0.00E+00	254.900	0.000
4	0.00E+00	282.700	0.000
5	0.00E+00	351.000	0.000
6	0.00E+00	246.700	0.000
7	0.00E+00	307.800	0.000
8	5.47E-20	282.000	0.000
9	1.38E-19	162.300	0.000
10	1.76E-18	389.800	0.000
11	2.29E-18	146.800	0.000
12	7.02E-18	193.700	0.000
13	2.79E-17	267.100	0.000
14	7.94E-17	268.400	0.000
15	6.62E-17	119.700	0.000
16	6.06E-17	80.9800	0.000
17	8.46E-17	88.7100	0.000
18	2.20E-16	164.300	0.000
19	2.60E-16	136.800	0.000
20	3.91E-16	152.300	0.000

Total	1.20E-15	4297.79	0.000
80 Perc. (17/16)	1.45E-16	169.690	0.000

Results for METABOLITE C1 (RH-163353) in the percolate at the bottom of the simulated soil core

Period	Metab.C1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	3.27E-13	274.900	0.000
2	2.14E-12	126.900	0.000
3	6.76E-11	254.900	0.000
4	9.78E-10	282.700	0.000
5	7.88E-09	351.000	0.000
6	1.70E-08	246.700	0.000
7	6.14E-08	307.800	0.000
8	1.76E-07	282.000	0.000
9	2.08E-07	162.300	0.000
10	1.00E-06	389.800	0.000

11	5.65E-07	146.800	0.000
12	8.46E-07	193.700	0.000
13	1.22E-06	267.100	0.000
14	1.18E-06	268.400	0.000
15	5.11E-07	119.700	0.000
16	3.45E-07	80.9800	0.000
17	3.82E-07	88.7100	0.000
18	7.44E-07	164.300	0.000
19	6.73E-07	136.800	0.000
20	8.13E-07	152.300	0.000

Total	8.75E-06	4297.79	0.000
80 Perc.(18/14)	1.92E-06	432.700	0.000

Results for METABOLITE B2 (RH-141455) in the percolate at the bottom of the simulated soil core

Period	Metab.B2 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)

1	0.0033040	274.900	0.001
2	0.0038160	126.900	0.003
3	0.0087230	254.900	0.003
4	0.0102200	282.700	0.004
5	0.0166800	351.000	0.005
6	0.0214400	246.700	0.009
7	0.0317000	307.800	0.010
8	0.0231400	282.000	0.008
9	0.0140500	162.300	0.009
10	0.0342700	389.800	0.009
11	0.0095710	146.800	0.007
12	0.0100200	193.700	0.005
13	0.0285800	267.100	0.011
14	0.0224300	268.400	0.008
15	0.0080400	119.700	0.007
16	0.0074530	80.9800	0.009
17	0.0103700	88.7100	0.012
18	0.0212600	164.300	0.013
19	0.0147600	136.800	0.011
20	0.0101000	152.300	0.007

Total	0.3099270	4297.79	0.007
80 Perc.(13/7)	0.0602800	574.900	0.010

MACRO–Output file (RH-141455, Châteaudun, potato)

Period	Av_FluxConc_at_reporting_depth
1	5.755388E-07
2	0.0003028999
3	0.002075285
4	0.001485459
5	0.006445075
6	0.01488128
7	0.009536047
8	0.009589849
9	0.009586008
10	0.0117909
11	0.009015087
12	0.008688885
13	0.007857013
14	0.01248845
15	0.02066062
16	0.01400652
17	0.02588136
18	0.001770748
19	0.004116303
20	0.01289045
21	0.0007244751
22	0.0003062593
23	0.002062673
24	0.001485994
25	0.006445215
26	0.01488159

STEP 1_2:- Output file (zoxamide, potato, Northern Europe)

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Predictions Step 2

developed by Michael Klein

Program version:	Version 3.2
Date of this simulation:	23.11.2020, 15:14:24

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: Zoxamide Potato Northern Europe 3 apps with 7 days interval

Active substance:	Zoxamide Potato north
Application rate (g/ha) of a.i.:	148.50
Crop Interception:	minimal crop cover (15 %)
Application/crop type:	potatoes
Number of applications per season:	3
Application interval (d):	7.00
Region and season of application:	North Europe, Mar. - May
Water solubility (mg/L):	0.68
KOC assessed compound(L/kg):	1179.00
KOC parent compound(L/kg):	1179.00
DT50 water(d):	6.40
DT50 sediment (d):	6.40
DT50 soil (d):	5.50

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.0240
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run:	3
Equivalent application rate for drift (g/ha):	148.50
Equivalent application rate for runoff/drainage(g/ha):	126.23
Loading to water body per drift event(mg/m²):	0.3006
Loading to water body via runoff/drainage (mg/m²):	2.4172
fraction of substance entering water body in water phase:	0.3888
fraction of substance entering water body in sediment:	0.6112
Total Loading to water body via drift (mg/m²):	0.9017 (27.1681%)
Total Loading to water body via water phase(mg/m²):	0.9398 (28.3172%)
Total Loading to water body via sediment phase (mg/m²):	1.4774 (44.5147%)
Maximum residue in sediment (%):	50.5732 on day 18
Maximum PECSW (µg/L):	3.6688
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	41.1398
Maximum PECsed occurring on day:	18

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	3.6688	---	41.1398	---
1	3.1938	3.4313	37.6551	39.3974
2	2.8660	3.2306	33.7899	37.5600
4	2.3078	2.9050	27.2092	33.9853
7	1.6676	2.5053	19.6611	29.3861
14	0.7813	1.8377	9.2120	21.5911
21	0.3661	1.4079	4.3162	16.5488
28	0.1715	1.1201	2.0223	13.1687
42	0.0377	0.7762	0.4440	9.1265
50	0.0158	0.6561	0.1867	7.7138
100	0.0001	0.3295	0.0008	3.8741

RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	148.50
Equivalent application rate for runoff/drainage(g/ha):	126.23
Loading to water body per drift event(mg/m²):	0.4097
Loading to water body via runoff(mg/m²):	1.5249
fraction of substance entering water body in water phase:	0.3888
fraction of substance entering water body in sediment phase:	0.6112
Total Loading to water body via drift (mg/m²):	0.4097 (21.1779%)
Total Loading to water body via water phase(mg/m²):	0.5929 (30.6462%)
Total Loading to water body via sediment phase (mg/m²):	0.9320 (48.1759%)
Maximum PECsw (µg/L):	2.4095
Maximum PECsw occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	26.6933
Maximum PECsed occurring on day:	4

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	2.4095	---	26.6933	---
1	2.0824	2.2459	24.5515	25.6224
2	1.8687	2.1107	22.0314	24.4569
4	1.5047	1.8962	17.7407	22.1425
7	1.0873	1.6347	12.8193	19.1507
14	0.5094	1.1988	6.0064	14.0730
21	0.2387	0.9184	2.8142	10.7869
28	0.1118	0.7307	1.3186	8.5838
42	0.0246	0.5063	0.2895	5.9490
50	0.0103	0.4279	0.1217	5.0282
100	0.0000	0.2149	0.0005	2.5253

SWASH–Output file (zoxamide, potato, multiple applications)

```
* SWASH report file
* made by FOCUS-SWASH UI v. 5 (internal version 5.1.0, 02 April 2015)
*
* File Name      : C:\SwashProjects\ZOX_P02_M\ZOX_P02_M_report.txt
* Description    : Reboot zoxamide potatoes
* Substance      : ZOX
* Creation       : 19-Nov-2020, 13:24
* Remarks       : SWASH report helps you to set up the needed runs to calculate the PECsw and PECsed, occurring in the EU
                  for the selected substance, used on the selected crop. The scenario code informs you which models you need to
                  run for this scenario.
                  D1-D6: drainage entries calculated by the MACRO model, fate in surface water calculated by the TOXSWA model
                  R1-R4: runoff and erosion entries calculated by the PRZM model, fate in surface water calculated by the TOXSWA
model
*               For STREAMS the Mean Deposition and Mass Loading, as calculated by the FOCUS Drift Calculator, have been
multiplied by a
*               factor 1.2 to account for pesticide mass incoming from the upstream catchment as decided by the FOCUS Surface
Water
*               Scenarios Working Group.

*****
*
*   CREATED RUNS
*****
*
*
*   |----- APPLICATION -----|---- on Water Surface
----|
* -ID-----Crop(1st/2nd)-----Scenario-WaterbodyType-|-Method-----First/Last/Interval--#---Rate-|-Mean Deposition-Mass
Loading
                                     (d)          (kg/ha) (% of Appl. Rate)
(mg/m2)
*
* 531 Potatoes(1st)          D3_Ditch          ground spray   30-May/13-Jul/7      1 0.1485      1.158
0.172
*
*                                     2 0.1485      1.158
0.172
*
*                                     3 0.1485      1.158
0.172
*
* 532 Potatoes(1st)          D4_Pond          ground spray   17-Jun/31-Jul/7      1 0.1485      0.149
0.022
*
*                                     2 0.1485      0.149
0.022
*
*                                     3 0.1485      0.149
0.022
*
* 533 Potatoes(1st)          D4_Stream         ground spray   17-Jun/31-Jul/7      1 0.1485      1.077
0.160
*
*                                     2 0.1485      1.077
0.160
*
*                                     3 0.1485      1.077
0.160
*
* 534 Potatoes(1st)          D6_Ditch          ground spray   24-Apr/7-Jun /7      1 0.1485      1.158
0.172
*
*                                     2 0.1485      1.158
0.172
*
*                                     3 0.1485      1.158
0.172
*
* 535 Potatoes(2nd)          D6_Ditch          ground spray   21-Aug/4-Oct /7      1 0.1485      1.158
0.172
*
*                                     2 0.1485      1.158
0.172
*
*                                     3 0.1485      1.158
0.172
*
* 536 Potatoes(1st)          R1_Pond          ground spray   20-May/3-Jul /7      1 0.1485      0.149
0.022
*
*                                     2 0.1485      0.149
0.022
*
*                                     3 0.1485      0.149
0.022
*
* 537 Potatoes(1st)          R1_Stream         ground spray   20-May/3-Jul /7      1 0.1485      1.077
0.160
*
*                                     2 0.1485      1.077
0.160
*
*                                     3 0.1485      1.077
0.160
*
* 538 Potatoes(1st)          R2_Stream         ground spray   6-Apr /20-May/7      1 0.1485      1.077
0.160
*
*                                     2 0.1485      1.077
0.160
*
*                                     3 0.1485      1.077
0.160
*
* 539 Potatoes(1st)          R3_Stream         ground spray   24-Apr/7-Jun /7      1 0.1485      1.077
0.160
*
*                                     2 0.1485      1.077
0.160
*
*                                     3 0.1485      1.077
0.160
*
***** Surface WAter Scenarios Help
*****
```

Toxswa –Output file (zoxamide, step 3, potato, D3 ditch scenario)

```

* -----
* TOXSWA REPORT: Header

* Results from the TOXSWA model (c) Wageningen University & Research
* FOCUS TOXSWA version : 5.5.3
* TOXSWA model version : 3.3.6
* TOXSWA created on : 17-Dec-2017

* Working directory : C:\SwashProjects\ZOX_PO2_M\TOXSWA
* Run ID : 531
* Input file generated on : 19-11-2020
* -----

* Scenario : D3_Ditch
* Meteo Station : Vredepeel
* Substance : ZOX
* Flow Type : Transient
* Water Body Type : D3_DITCH
* Application Scheme : FOCUS_EXAMPLE
* Simulation Period : 01-Jan-1992 to 30-Apr-1993
* -----
* End of TOXSWA REPORT: Header
* -----

* -----
* TOXSWA REPORT: Substance properties and substance loadings

* Summary for the following substances

* Substance 1: ZOX
* Molar mass (g.mol-1) : 336.6
* Saturated vapour pressure (Pa) : 0.130E-04 measured at (C) : 25.0
* Water solubility (mg.L-1) : 0.681E+00 measured at (C) : 20.0
* Half-life in water, lumped (d): 1000.00 at reference temperature (C) : 20.0
* Half-life in sediment (d) : 6.40 at reference temperature (C) : 20.0
* Kom susp.solids (Freundlich coef. for sorption on organic matter) (L.kg-1) : 684.00
* Freundlich exponent (-) : 0.97
* Kom sediment (Freundlich coef. for sorption on organic matter) (L.kg-1) : 684.00
* Freundlich exponent (-) : 0.97
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00

* Summary for the substance loadings

* Application pattern and deposition by drift on water surface
* Appl.No Date/Hour Mass (g ai.ha-1) Areic mean deposition (mg.m-2)
* 1 14-Jun-1992-09h00 148.5000 0.1720
* 2 26-Jun-1992-09h00 148.5000 0.1720
* 3 08-Jul-1992-09h00 148.5000 0.1720

* Lateral entry: drainage Simulated by: MACRO

* Maximum hourly fluxes from lateral entries
* Year Type Water/Substance Flux Date
* 1992 Water 0.09006 mm.m-2.hr-1 09-Jan-1992-00h30
* 1992 Drainage ZOX < 1e-6 mg.m-2.hr-1 01-Jan-1992-00h00
* 1992 Drainage ZOX < 1e-6 ug.L-1 01-Jan-1992-00h00
* 1993 Water 0.05996 mm.m-2.hr-1 20-Jan-1993-01h30
* 1993 Drainage ZOX < 1e-6 mg.m-2.hr-1 01-Jan-1993-00h00
* 1993 Drainage ZOX < 1e-6 ug.L-1 01-Jan-1993-00h00
* -----
* End of TOXSWA REPORT: Substance properties and substance loadings
* -----

* -----
* TOXSWA REPORT: Water and mass balances

* Table: Water balance of the water body
* Key to the table
* -----
* DelSto Change in volume present in water layer (m3)
* VolPrc Volume entered in water body by precipitation (m3)
* VolDra Volume entered in water body by drainage (m3)
* VolRun Volume entered in water body by runoff (m3)
* VolUps Volume flowed into water body across upstream boundary (m3)
* VolDwn Volume flowed out of water body across downstream boundary (m3)
* -----

* Monthly water balance terms (m3) in water system of 100.00 m
* -----
* Year Month Identifier DelSto VolPrc VolDra VolRun VolUps VolDwn
* -----

```

1992	Jan	BalWatLay	-0.0380	0.0000	597.2769	0.0000	1201.1126	1798.4472
1992	Feb	BalWatLay	-0.0770	0.0000	413.6720	0.0000	833.5414	1247.3435
1992	Mar	BalWatLay	-0.0720	0.0000	351.1660	0.0000	708.9358	1060.2196
1992	Apr	BalWatLay	-0.0440	0.0000	293.0915	0.0000	592.5357	885.6979
1992	May	BalWatLay	-0.0300	0.0000	255.8526	0.0000	518.2488	774.1508
1992	Jun	BalWatLay	0.0390	0.0000	267.2279	0.0000	540.7082	807.8772
1992	Jul	BalWatLay	-0.0170	0.0000	279.3702	0.0000	565.2701	844.6676
1992	Aug	BalWatLay	-0.0170	0.0000	240.9385	0.0000	488.4053	729.3727
1992	Sep	BalWatLay	0.0730	0.0000	332.7550	0.0000	671.7208	1004.3579
1992	Oct	BalWatLay	0.0820	0.0000	297.6195	0.0000	601.6415	899.1259
1992	Nov	BalWatLay	0.0420	0.0000	450.8691	0.0000	907.9812	1358.7781
1992	Dec	BalWatLay	-0.0560	0.0000	435.1982	0.0000	876.9824	1312.2762
1993	Jan	BalWatLay	0.0310	0.0000	414.8304	0.0000	836.1293	1250.9065
1993	Feb	BalWatLay	-0.0720	0.0000	360.3192	0.0000	726.6131	1087.0541
1993	Mar	BalWatLay	-0.0730	0.0000	320.3004	0.0000	647.2011	967.6197
1993	Apr	BalWatLay	-0.0650	0.0000	231.4218	0.0000	469.2168	700.7411

* Annual water balance terms (m3) in water system of 100.00 m

* (year may be incomplete)

* Year	Identifier	DelSto	VolPrc	VolDra	VolRun	VolUps	VolDwn
1992	BalWatLay	-0.1150	0.0000	4215.0373	0.0000	8507.0838	12722.3145
1993	BalWatLay	-0.1790	0.0000	1326.8717	0.0000	2679.1603	4006.3213

* Table: Mass balance of substance in the water layer

* Key to the table

* DelMas	Change in mass present in water layer system (g)
* MasIni	Mass initially present in water layer (g)
* MasDrf	Loading of water body by drift (g)
* MasAtmDep	Loading of water body by atmospheric deposition (g)
* MasDra	Loading of water body by drainage (g)
* MasRnf	Loading of water body by run-off (g)
* MasSedIn	Mass penetrated into sediment (g)
* MasSedOut	Mass transferred out of sediment (g)
* MasDwn	Mass flowed across downstream boundary end (g)
* MasUps	Mass flowed across upstream boundary (g)
* MasTra	Mass transformed in water layer (g)
* MasFor	Mass formed in water layer (g)
* MasVol	Mass volatilised from water layer (g)

* Monthly mass balance terms (g) in entire water layer of water body system of 100.00 m for substance:

ZOX

* Year	Month	DelMas	MasIni	MasDrf	MasAtmDep	MasDra	MasRnf	MasSedIn	MasSedOut
MasDwn	MasUps	MasTra	MasFor	MasVol					
1992	Jan	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Feb	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Mar	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Apr	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	May	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Jun	0.0000	0.0000	0.0344	0.0000	0.0000	0.0000	-0.0016	0.0008
-0.0335	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	-0.0016	0.0008
1992	Jul	-0.0000	0.0000	0.0172	0.0000	0.0000	0.0000	-0.0008	0.0006
-0.0169	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	-0.0008	0.0006
1992	Aug	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Sep	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Oct	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Nov	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Dec	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1993	Jan	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1993	Feb	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1993	Mar	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1993	Apr	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

* -----									
* Annual mass balance terms (g) in water layer of water body system of 100.00 m for substance: ZOX									
* (years may be incomplete									
* Year	DelMas	MasIni	MasDrf	MasAtmDep	MasDra	MasRnf	MasSedIn	MasSedOut	
MasDwn	MasUps	MasTra	MasFor	MasVol					

1992	0.0000	0.0000	0.0516	0.0000	0.0000	0.0000	-0.0025	0.0013	-
0.0504	0.0000	-0.0000	0.0000	-0.0000					
1993	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	-
0.0000	0.0000	-0.0000	0.0000	-0.0000					

* -----									
* Table: Mass balance of substance in the sediment									
Key to the table									

* DelMasSed	Change in mass present in sediment system (g)								
* MasIniSed	Mass initially present in sediment (g)								
* MasErs	Loading of sediment by erosion (g)								
* MasWatIn	Mass transferred to water layer (g)								
* MasWatOut	Mass transferred from water layer (g)								
* MasDwnSed	Mass flowed across boundary to deeper layers (g)								
* MasTraSed	Mass transformed in sediment (g)								
* MasFor	Mass formed in sediment (g)								

* -----									
* Monthly mass balance terms (g) in sediment of water body system of 100.00 m for substance: ZOX									
* Year	Month	DelMasSed	MasIniSed	MasErs	MasWatIn	MasWatOut	MasDwnSed	MasTra	MasFor

1992	Jan	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Feb	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Mar	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Apr	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	May	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1992	Jun	0.0003	0.0000	0.0000	-0.0008	0.0016	0.0000	-0.0005	0.0000
1992	Jul	-0.0003	0.0003	0.0000	-0.0006	0.0008	0.0000	-0.0006	0.0000
1992	Aug	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000
1992	Sep	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000
1992	Oct	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000
1992	Nov	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000
1992	Dec	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000
1993	Jan	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000
1993	Feb	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000
1993	Mar	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000
1993	Apr	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000

* -----									
* Annual mass balance terms (g) in sediment of water body system of 100.00 m for substance: ZOX									
* (years may be incomplete									
* Year	DelMasSed	MasIniSed	MasErs	MasWatIn	MasWatOut	MasDwnSed	MasTraSed	MasForSed	

1992	0.0000	0.0000	0.0000	-0.0013	0.0025	0.0000	-0.0011	0.0000	
1993	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	

* -----									
* End of TOXSWA REPORT: Water and mass balances									

* -----									
* TOXSWA REPORT: Exposure in water body									
* -----									
* Table: Annual maximum exposure concentrations in water layer of substance: ZOX									
* In segment from 90.00 to 100.00 m in water body									
* -----									
* Year	Concentration	Date	Daynr						
	µg.L-1		(since start simulation)						

1992	0.5653	08-Jul-1992-09h00	190						
1993	< 1e-6	01-Jan-1993-00h00	366						

* -----									
* Tables: Maximum exposure concentrations in water layer									
* In segment from 90.00 to 100.00 m in water body									
* Actual concentrations PECsw as well as PECsed refer to momentary concentrations									
* occurring 1, 2 etc days after the global maximum concentration.									
* The Time Weighted Average Exposure Concentrations (TWAEC) have been calculated									
* for a moving time frame and have been allocated to the last moment of the period considered									

* Table: PEC in water layer of substance: ZOX

	Concentration µg.L-1	Date	Daynr (since start simulation)
Global max	0.5653	08-Jul-1992-09h00	190
(incl. suspend.solid)	0.5659	08-Jul-1992-09h00	190)
PECsw_1_day	0.2835	09-Jul-1992-09h00	191
PECsw_2_days	0.04382	10-Jul-1992-09h00	192
PECsw_3_days	0.007975	11-Jul-1992-09h00	193
PECsw_4_days	0.003066	12-Jul-1992-09h00	194
PECsw_7_days	0.000694	15-Jul-1992-09h00	197
PECsw_14_days	0.000104	22-Jul-1992-09h00	204
PECsw_21_days	0.000029	29-Jul-1992-09h00	211
PECsw_28_days	0.000010	05-Aug-1992-09h00	218
PECsw_42_days	0.000002	19-Aug-1992-09h00	232
PECsw_50_days	< 1e-6	27-Aug-1992-09h00	240
PECsw_100_days	< 1e-6	16-Oct-1992-09h00	290

* Legend: - in table means PECsw is later than end of simulated period: 30-Apr-1993

* Table: Maximum Time Weighted Averaged Exposure Concentrations substance: ZOX

	Concentration µg.L-1	Date	Daynr (since start simulation)
TWAECSw_1_day	0.4444	09-Jul-1992-09h00	191
TWAECSw_2_days	0.2892	10-Jul-1992-09h00	192
TWAECSw_3_days	0.1994	11-Jul-1992-09h00	193
TWAECSw_4_days	0.1508	12-Jul-1992-09h00	194
TWAECSw_7_days	0.08679	15-Jul-1992-09h00	197
TWAECSw_14_days	0.08372	10-Jul-1992-09h00	192
TWAECSw_21_days	0.05725	17-Jul-1992-09h00	199
TWAECSw_28_days	0.06370	12-Jul-1992-09h00	194
TWAECSw_42_days	0.04262	26-Jul-1992-09h00	208
TWAECSw_50_days	0.03581	03-Aug-1992-09h00	216
TWAECSw_100_days	0.01790	22-Sep-1992-09h00	266

* Tables: Maximum exposure content in sediment

* In the top 5.00 cm sediment located under
* the water body segment from 90.00 to 100.00 m,
* the content is expressed as µg substance per kg dry sediment.

* Table: PEC in sediment of substance: ZOX

	Content µg.kg-1	Date	Daynr (since start simulation)
Global max	0.3031	09-Jul-1992-16h00	191
PECsed_1_day	0.2447	10-Jul-1992-16h00	192
PECsed_2_days	0.1809	11-Jul-1992-16h00	193
PECsed_3_days	0.1391	12-Jul-1992-16h00	194
PECsed_4_days	0.1112	13-Jul-1992-16h00	195
PECsed_7_days	0.06475	16-Jul-1992-16h00	198
PECsed_14_days	0.02414	23-Jul-1992-16h00	205
PECsed_21_days	0.01019	30-Jul-1992-16h00	212
PECsed_28_days	0.004553	06-Aug-1992-16h00	219
PECsed_42_days	0.000985	20-Aug-1992-16h00	233
PECsed_50_days	0.000421	28-Aug-1992-16h00	241
PECsed_100_days	0.000015	17-Oct-1992-16h00	291

* Legend: - in table means PECsed is later than end of simulated period: 30-Apr-1993

* Table: Maximum Time Weighted Averaged Exposure Content substance: ZOX

	Content µg.kg-1	Date	Daynr (since start simulation)
TWAECSed_1_day	0.2941	10-Jul-1992-05h00	192
TWAECSed_2_days	0.2728	10-Jul-1992-23h00	192
TWAECSed_3_days	0.2484	11-Jul-1992-18h00	193
TWAECSed_4_days	0.2255	12-Jul-1992-15h00	194
TWAECSed_7_days	0.1740	15-Jul-1992-11h00	197
TWAECSed_14_days	0.1449	10-Jul-1992-23h00	192
TWAECSed_21_days	0.1349	17-Jul-1992-10h00	199
TWAECSed_28_days	0.1313	12-Jul-1992-18h00	194
TWAECSed_42_days	0.1050	26-Jul-1992-10h00	208
TWAECSed_50_days	0.08994	03-Aug-1992-09h00	216
TWAECSed_100_days	0.04557	22-Sep-1992-09h00	266

* End of TOXSWA REPORT: Exposure in water body

* The run time was 1 minutes and 4 seconds

SWAN-Logfile (zoxamide, potato, multiple applications, 10 m buffer)

```
*-----
*
* SWAN log file
* Created by SWAN v5.0.1 at 20-Nov-2020, 10:56:30
*
* Processing parameter file: C:\SwashProjects\ZOX_PO2_M_10_00%\ZOX_PO2_M_10_00%.tpf
*
*-----
*
Loaded parameter file: C:\SwashProjects\ZOX_PO2_M_10_00%\ZOX_PO2_M_10_00%.tpf

Loading source project: C:\SwashProjects\ZOX_PO2_M
Loaded TOXSWA file: 531.twx
Loaded TOXSWA file: 532.twx
Loaded TOXSWA file: 533.twx
Loaded TOXSWA file: 534.twx
Loaded TOXSWA file: 535.twx
Loaded TOXSWA file: 536.twx
Loaded TOXSWA file: 537.twx
Loaded TOXSWA file: 538.twx
Loaded TOXSWA file: 539.twx
Loaded support file: macro00531_p.m2t
Loaded support file: macro00533_p.m2t
Loaded support file: macro00533_p.m2t
Loaded support file: macro00534_p.m2t
Loaded support file: macro00535_p.m2t
Loaded support file: 00537-C1.p2t
Loaded support file: 00537-C1.p2t
Loaded support file: 00538-C1.p2t
Loaded support file: 00539-C1.p2t
Load complete

Validating...
WARNING: User selections mean that dry deposition mitigation will not be applied even though spray drift
mitigation is being applied and the vapour pressure is greater than or equal to the threshold (1E-05 Pa) for
scenario D3 with water body Ditch.
WARNING: User selections mean that dry deposition mitigation will not be applied even though spray drift
mitigation is being applied and the vapour pressure is greater than or equal to the threshold (1E-05 Pa) for
scenario D4 with water body Pond.
WARNING: User selections mean that dry deposition mitigation will not be applied even though spray drift
mitigation is being applied and the vapour pressure is greater than or equal to the threshold (1E-05 Pa) for
scenario D4 with water body Stream.
WARNING: User selections mean that dry deposition mitigation will not be applied even though spray drift
mitigation is being applied and the vapour pressure is greater than or equal to the threshold (1E-05 Pa) for
scenario D6 with water body Ditch.
WARNING: User selections mean that dry deposition mitigation will not be applied even though spray drift
mitigation is being applied and the vapour pressure is greater than or equal to the threshold (1E-05 Pa) for
scenario R1 with water body Pond.
WARNING: User selections mean that dry deposition mitigation will not be applied even though spray drift
mitigation is being applied and the vapour pressure is greater than or equal to the threshold (1E-05 Pa) for
scenario R1 with water body Stream.
WARNING: User selections mean that dry deposition mitigation will not be applied even though spray drift
mitigation is being applied and the vapour pressure is greater than or equal to the threshold (1E-05 Pa) for
scenario R2 with water body Stream.
WARNING: User selections mean that dry deposition mitigation will not be applied even though spray drift
mitigation is being applied and the vapour pressure is greater than or equal to the threshold (1E-05 Pa) for
scenario R3 with water body Stream.
Validation complete
*
*-----
*
* Run-off mitigation
*-----
*
Reduction run-off mode: ManualReduction
Fractional reduction in run-off volume: 0.6
Fractional reduction in run-off flux: 0.6
Fractional reduction in erosion mass: 0.85
Fractional reduction in erosion flux: 0.85

Run-off mitigation has been applied to: 00537-C1_pond.p2t
Run-off mitigation has been applied to: 00537-C1_stream.p2t
Run-off mitigation has been applied to: 00538-C1.p2t
Run-off mitigation has been applied to: 00539-C1.p2t
*
*-----
*
* Spray drift mitigation
*-----
*
Nozzle reduction (%): 0

Use Step 3 mass loadings: No

Select buffer width: Yes
```

Buffer width (m): 10

Enter mass loadings directly: No
Pond mass loading (mg/m²): 0
Ditch mass loading (mg/m²): 0
Stream mass loading (mg/m²): 0

Spray drift mitigation has been applied to: 531.twx
Spray drift mitigation has been applied to: 532.twx
Spray drift mitigation has been applied to: 533.twx
Spray drift mitigation has been applied to: 534.twx
Spray drift mitigation has been applied to: 535.twx
Spray drift mitigation has been applied to: 536.twx
Spray drift mitigation has been applied to: 537.twx
Spray drift mitigation has been applied to: 538.twx
Spray drift mitigation has been applied to: 539.twx

*

*-----

*

* Dry deposition after volatilisation

*-----

*

Dry deposition mitigation was not applied to any file

*

*-----

*

Saving mitigated project: C:\SwashProjects\ZOX_PO2_M_10_00%

Saved TOXSWA file: 531.twx

Saved TOXSWA file: 532.twx

Saved TOXSWA file: 533.twx

Saved TOXSWA file: 534.twx

Saved TOXSWA file: 535.twx

Saved TOXSWA file: 536.twx

Saved TOXSWA file: 537.twx

Saved TOXSWA file: 538.twx

Saved TOXSWA file: 539.twx

Saved m2t file: macro00531_p.m2t

Saved m2t file: macro00533_p_pond.m2t

Saved m2t file: macro00533_p_stream.m2t

Saved m2t file: macro00534_p.m2t

Saved m2t file: macro00535_p.m2t

Saved p2t file: 00537-C1_pond.p2t

Saved p2t file: 00537-C1_stream.p2t

Saved p2t file: 00538-C1.p2t

Saved p2t file: 00539-C1.p2t

Saved updated MACRO/PRZM files. Copying auxiliary files...

Saving files for crop Potatoes

Copying .inp files..

Copying C:\SwashProjects\ZOX_PO2_M\PRZM\potatoes\R1-PS-.INP to

C:\SwashProjects\ZOX_PO2_M_10_00%\PRZM\potatoes\R1-PS-.INP

Copying C:\SwashProjects\ZOX_PO2_M\PRZM\potatoes\R2-PS-.INP to

C:\SwashProjects\ZOX_PO2_M_10_00%\PRZM\potatoes\R2-PS-.INP

Copying C:\SwashProjects\ZOX_PO2_M\PRZM\potatoes\R3-PS-.INP to

C:\SwashProjects\ZOX_PO2_M_10_00%\PRZM\potatoes\R3-PS-.INP

Copying .zts files..

Copying C:\SwashProjects\ZOX_PO2_M\PRZM\potatoes\R1-PS-.ZTS to

C:\SwashProjects\ZOX_PO2_M_10_00%\PRZM\potatoes\R1-PS-.ZTS

Copying C:\SwashProjects\ZOX_PO2_M\PRZM\potatoes\R2-PS-.ZTS to

C:\SwashProjects\ZOX_PO2_M_10_00%\PRZM\potatoes\R2-PS-.ZTS

Copying C:\SwashProjects\ZOX_PO2_M\PRZM\potatoes\R3-PS-.ZTS to

C:\SwashProjects\ZOX_PO2_M_10_00%\PRZM\potatoes\R3-PS-.ZTS

Save complete

Copied Bologna.met

Copied Porto.met

Copied Skousbo.met

Copied Thiva.met

Copied Vredepeel.met

Copied Weiherbach.met

Copied ZOX_PO2_M_report.txt

Generated TOXSWA batch file: C:\SwashProjects\ZOX_PO2_M_10_00%\TOXSWA\TOXSWABat.bat

*

*-----

*

* Completed in 13.6 seconds

*

*-----

Toxswa –Output file (zoxamide, step 4, potato, R3 stream scenario, 10 m buffer)

```

* -----
* TOXSWA REPORT: Header

* Results from the TOXSWA model (c) Wageningen University & Research
* FOCUS TOXSWA version : 5.5.3
* TOXSWA model version : 3.3.6
* TOXSWA created on : 17-Dec-2017

* Working directory : C:\SwashProjects\ZOX_PO2_M_10_00%\TOXSWA
* Run ID : 539
* Input file generated on : 20-11-2020
* -----

* Scenario : R3_Stream
* Meteo Station : Bologna
* Substance : ZOX
* Flow Type : Transient
* Water Body Type : R3_STREAM
* Application Scheme : FOCUS_EXAMPLE
* Simulation Period : 01-Mar-1980 to 28-Feb-1981
* -----
* End of TOXSWA REPORT: Header
* -----

* -----
* TOXSWA REPORT: Substance properties and substance loadings

* Summary for the following substances

* Substance 1: ZOX
* Molar mass (g.mol-1) : 336.6
* Saturated vapour pressure (Pa) : 0.130E-04 measured at (C) : 25.0
* Water solubility (mg.L-1) : 0.681E+00 measured at (C) : 20.0
* Half-life in water, lumped (d): 1000.00 at reference temperature (C) : 20.0
* Half-life in sediment (d) : 6.40 at reference temperature (C) : 20.0
* Kom susp.solids (Freundlich coef. for sorption on organic matter) (L.kg-1) : 684.00
* Freundlich exponent (-) : 0.97
* Kom sediment (Freundlich coef. for sorption on organic matter) (L.kg-1) : 684.00
* Freundlich exponent (-) : 0.97
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00

* Summary for the substance loadings

* Application pattern and deposition by drift on water surface
* Appl.No Date/Hour Mass (g ai.ha-1) Areic mean deposition (mg.m-2)
* 1 24-Apr-1980-09h00 148.5000 0.0347
* 2 18-May-1980-09h00 148.5000 0.0347
* 3 01-Jun-1980-09h00 148.5000 0.0347

* Lateral entries: runoff and erosion Simulated by: PRZM

* Maximum hourly fluxes from lateral entries
* Year Type Water/Substance Flux Date
* 1980 Water 1.006 mm.m-2.hr-1 27-Nov-1980-00h30
* 1980 Runoff ZOX 0.000091 mg.m-2.hr-1 23-May-1980-00h30
* 1980 Runoff ZOX 1.564 ug.L-1 23-May-1980-00h30
* 1980 Erosion ZOX 0.000003 mg.m-2.hr-1 23-May-1980-00h30
* 1981 Water 0.03714 mm.m-2.hr-1 11-Feb-1981-00h30
* 1981 Runoff ZOX < 1e-6 mg.m-2.hr-1 11-Feb-1981-00h30
* 1981 Runoff ZOX < 1e-6 ug.L-1 13-Jan-1981-00h30
* 1981 Erosion ZOX < 1e-6 mg.m-2.hr-1 11-Feb-1981-00h30
* -----
* End of TOXSWA REPORT: Substance properties and substance loadings
* -----

* -----
* TOXSWA REPORT: Water and mass balances

* Table: Water balance of the water body
* Key to the table
* -----
* DelSto Change in volume present in water layer (m3)
* VolPrc Volume entered in water body by precipitaton (m3)
* VolDra Volume entered in water body by drainage (m3)
* VolRun Volume entered in water body by runoff (m3)
* VolUps Volume flowed into water body across upstream boundary (m3)
* VolDwn Volume flowed out of water body across downstream boundary (m3)
* -----

* Monthly water balance terms (m3) in water system of 100.00 m
* -----

```

* Year	Month	Identifier	DelSto	VolPrc	VolDra	VolRun	VolUps	VolDwn
*								
1980	Mar	BalWatLay	0.0000	0.0000	0.0000	0.0000	10438.9518	10569.7647
1980	Apr	BalWatLay	-0.0910	0.0000	0.0000	0.0000	7040.7557	7104.6304
1980	May	BalWatLay	0.0410	0.0000	0.0000	0.0000	3523.6708	3540.9220
1980	Jun	BalWatLay	-0.0980	0.0000	0.0000	0.0000	7353.5245	7420.6733
1980	Jul	BalWatLay	0.0000	0.0000	0.0000	0.0000	10914.0421	11028.3735
1980	Aug	BalWatLay	0.0000	0.0000	0.0000	0.0000	8540.6257	8623.0381
1980	Sep	BalWatLay	0.0000	0.0000	0.0000	0.0000	3032.3878	3044.4618
1980	Oct	BalWatLay	0.0000	0.0000	0.0000	0.0000	9375.7937	9482.7712
1980	Nov	BalWatLay	0.7280	0.0000	0.0000	0.0000	49835.9958	50501.5685
1980	Dec	BalWatLay	-0.4610	0.0000	0.0000	0.0000	9690.8106	9808.1336
1981	Jan	BalWatLay	-0.2250	0.0000	0.0000	0.0000	2505.4422	2507.1158
1981	Feb	BalWatLay	-0.0390	0.0000	0.0000	0.0000	2291.5659	2295.2824
*								

* Annual water balance terms (m3) in water system of 100.00 m

* (year may be incomplete)

* Year	Identifier	DelSto	VolPrc	VolDra	VolRun	VolUps	VolDwn
*							
1980	BalWatLay	0.1190	0.0000	0.0000	0.0000	119746.5585	121124.3372
1981	BalWatLay	-0.2640	0.0000	0.0000	0.0000	4797.0081	4802.3982
*							

* Table: Mass balance of substance in the water layer

* Key to the table

*		
* DelMas	Change in mass present in water layer system (g)	
* MasIni	Mass initially present in water layer (g)	
* MasDrf	Loading of water body by drift (g)	
* MasAtmDep	Loading of water body by atmospheric deposition (g)	
* MasDra	Loading of water body by drainage (g)	
* MasRnf	Loading of water body by run-off (g)	
* MasSedIn	Mass penetrated into sediment (g)	
* MasSedOut	Mass transferred out of sediment (g)	
* MasDwn	Mass flowed across downstream boundary end (g)	
* MasUps	Mass flowed across upstream boundary (g)	
* MasTra	Mass transformed in water layer (g)	
* MasFor	Mass formed in water layer (g)	
* MasVol	Mass volatilised from water layer (g)	
*		

* Monthly mass balance terms (g) in entire water layer of water body system of 100.00 m for substance: ZOX

* Year	Month	DelMas	MasIni	MasDrf	MasAtmDep	MasDra	MasRnf	MasSedIn	MasSedOut
MasDwn	MasUps	MasTra	MasFor	MasVol					
*									
1980	Mar	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	-0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0001	0.0000
1980	Apr	0.0000	0.0000	0.0035	0.0000	0.0000	0.0000	-0.0001	0.0000
-0.0034	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0088	-0.0007	0.0004
1980	May	0.0000	0.0000	0.0035	0.0000	0.0000	0.0088	-0.0007	0.0004
-0.1873	0.1753	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0085	-0.0002	0.0002
1980	Jun	-0.0000	0.0000	0.0035	0.0000	0.0000	0.0085	-0.0002	0.0002
-0.1816	0.1697	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0003	-0.0000	0.0000
1980	Jul	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0003	-0.0000	0.0000
-0.0054	0.0051	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000
1980	Aug	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000
1980	Sep	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000
1980	Oct	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000
1980	Nov	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	0.0000	0.0000
1980	Dec	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1981	Jan	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1981	Feb	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

* Annual mass balance terms (g) in water layer of water body system of 100.00 m for substance: ZOX
* (years may be incomplete)

* Year	DelMas	MasIni	MasDrf	MasAtmDep	MasDra	MasRnf	MasSedIn	MasSedOut
MasDwn	MasUps	MasTra	MasFor	MasVol				

* -----									
1980	0.0000	0.0000	0.0104	0.0000	0.0000	0.0175	-0.0009	0.0006	-
0.3777	0.3501	-0.0000	0.0000	-0.0000					
1981	-0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	
0.0000	0.0000	0.0000	0.0000	0.0000					

* -----

* Table: Mass balance of substance in the sediment
* Key to the table

* -----	
* DelMasSed	Change in mass present in sediment system (g)
* MasIniSed	Mass initially present in sediment (g)
* MasErs	Loading of sediment by erosion (g)
* MasWatIn	Mass transferred to water layer (g)
* MasWatOut	Mass transferred from water layer (g)
* MasDwnSed	Mass flowed across boundary to deeper layers (g)
* MasTraSed	Mass transformed in sediment (g)
* MasFor	Mass formed in sediment (g)
* -----	

* -----										
* Monthly mass balance terms (g) in sediment of water body system of 100.00 m for substance: ZOX										
* Year	Month	DelMasSed	MasIniSed	MasErs	MasWatIn	MasWatOut	MasDwnSed	MasTra	MasFor	
* -----										
1980	Mar	0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	
1980	Apr	0.0000	0.0000	0.0000	-0.0000	0.0001	0.0000	-0.0000	0.0000	
1980	May	0.0001	0.0000	0.0001	-0.0004	0.0007	0.0000	-0.0002	0.0000	
1980	Jun	-0.0001	0.0001	0.0001	-0.0002	0.0002	0.0000	-0.0002	0.0000	
1980	Jul	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	
1980	Aug	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	
1980	Sep	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	
1980	Oct	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	
1980	Nov	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	
1980	Dec	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	
1981	Jan	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	
1981	Feb	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	

* -----

* -----									
* Annual mass balance terms (g) in sediment of water body system of 100.00 m for substance: ZOX									
* (years may be incomplete)									
* Year	DelMasSed	MasIniSed	MasErs	MasWatIn	MasWatOut	MasDwnSed	MasTraSed	MasForSed	
* -----									
1980	0.0000	0.0000	0.0001	-0.0006	0.0009	0.0000	-0.0004	0.0000	
1981	-0.0000	0.0000	0.0000	-0.0000	0.0000	0.0000	-0.0000	0.0000	

* End of TOXSWA REPORT: Water and mass balances

* TOXSWA REPORT: Exposure in water body

* Table: Annual maximum exposure concentrations in water layer of substance: ZOX
* In segment from 95.00 to 100.00 m in water body

* Year	Concentration	Date	Daynr
	µg.L-1		(since start simulation)
* -----			
1980	0.3122	23-May-1980-02h00	84
1981	< 1e-6	01-Jan-1981-16h00	307

* Tables: Maximum exposure concentrations in water layer
* In segment from 95.00 to 100.00 m in water body
* Actual concentrations PECsw as well as PECsed refer to momentary concentrations
* occurring 1, 2 etc days after the global maximum concentration.
* The Time Weighted Average Exposure Concentrations (TWAEC) have been calculated
* for a moving time frame and have been allocated to the last moment of the period considered

* Table: PEC in water layer of substance: ZOX

* -----			
	Concentration	Date	Daynr
	µg.L-1		(since start simulation)
* -----			
Global max	0.3122	23-May-1980-02h00	84
(incl. suspend.solid)	0.3125	23-May-1980-02h00	84)
PECsw_1_day	0.005420	24-May-1980-02h00	85
PECsw_2_days	0.000832	25-May-1980-02h00	86
PECsw_3_days	0.000452	26-May-1980-02h00	87
PECsw_4_days	0.04299	27-May-1980-02h00	88
PECsw_7_days	0.000251	30-May-1980-02h00	91

PECsw_14_days	0.000062	06-Jun-1980-02h00	98
PECsw_21_days	0.000011	13-Jun-1980-02h00	105
PECsw_28_days	0.000097	20-Jun-1980-02h00	112
PECsw_42_days	0.000006	04-Jul-1980-02h00	126
PECsw_50_days	0.000002	12-Jul-1980-02h00	134
PECsw_100_days	< 1e-6	31-Aug-1980-02h00	184

* -----
* Legend: - in table means PECsw is later than end of simulated period: 28-Feb-1981

* Table: Maximum Time Weighted Averaged Exposure Concentrations substance: ZOX

	Concentration µg.L-1	Date	Daynr (since start simulation)
TWAECSw_1_day	0.1836	24-May-1980-00h00	85
TWAECSw_2_days	0.09287	25-May-1980-00h00	86
TWAECSw_3_days	0.06213	26-May-1980-00h00	87
TWAECSw_4_days	0.04669	27-May-1980-00h00	88
TWAECSw_7_days	0.03739	30-May-1980-00h00	91
TWAECSw_14_days	0.02361	30-May-1980-00h00	91
TWAECSw_21_days	0.01799	03-Jun-1980-03h00	95
TWAECSw_28_days	0.01351	10-Jun-1980-01h00	102
TWAECSw_42_days	0.01048	27-Jun-1980-00h00	119
TWAECSw_50_days	0.008882	02-Jul-1980-01h00	124
TWAECSw_100_days	0.004876	02-Aug-1980-09h00	155

* Tables: Maximum exposure content in sediment

* In the top 5.00 cm sediment located under
* the water body segment from 95.00 to 100.00 m,
* the content is expressed as µg substance per kg dry sediment.

* Table: PEC in sediment of substance: ZOX

	Content µg.kg-1	Date	Daynr (since start simulation)
Global max	0.1337	23-May-1980-18h00	84
PECsed_1_day	0.09659	24-May-1980-18h00	85
PECsed_2_days	0.07251	25-May-1980-18h00	86
PECsed_3_days	0.05787	26-May-1980-18h00	87
PECsed_4_days	0.09424	27-May-1980-18h00	88
PECsed_7_days	0.04867	30-May-1980-18h00	91
PECsed_14_days	0.02374	06-Jun-1980-18h00	98
PECsed_21_days	0.009424	13-Jun-1980-18h00	105
PECsed_28_days	0.01982	20-Jun-1980-18h00	112
PECsed_42_days	0.004622	04-Jul-1980-18h00	126
PECsed_50_days	0.001813	12-Jul-1980-18h00	134
PECsed_100_days	0.000002	31-Aug-1980-18h00	184

* Legend: - in table means PECsed is later than end of simulated period: 28-Feb-1981

* Table: Maximum Time Weighted Averaged Exposure Content substance: ZOX

	Content µg.kg-1	Date	Daynr (since start simulation)
TWAECSed_1_day	0.1226	24-May-1980-11h00	85
TWAECSed_2_days	0.1081	25-May-1980-08h00	86
TWAECSed_3_days	0.09617	26-May-1980-06h00	87
TWAECSed_4_days	0.08697	27-May-1980-07h00	88
TWAECSed_7_days	0.08106	30-May-1980-05h00	91
TWAECSed_14_days	0.06193	06-Jun-1980-02h00	98
TWAECSed_21_days	0.04840	08-Jun-1980-11h00	100
TWAECSed_28_days	0.04069	20-Jun-1980-02h00	112
TWAECSed_42_days	0.03291	27-Jun-1980-09h00	119
TWAECSed_50_days	0.02896	05-Jul-1980-03h00	127
TWAECSed_100_days	0.01616	02-Aug-1980-09h00	155

*
* End of TOXSWA REPORT: Exposure in water body
* -----

EVA–Output (zoxamide)

physico-chemical data

vapour pressure meas. (Pa)	1.30E-05	substance is nonvolatile
at temperature (°C or K)	25 °C	
vapour pressure, 20 °C (Pa)	6.76E-06	
water solubility meas. (mg/L)	0.681	
at temperature (°C or K)	20 °C	
water solubility, 20 °C (mg/L)	0.681	

intended use parameters

active substance/product	Zoxamide	
intended use		
select critical applic. for v/d	final application rate	worst case for equal application rates and intervals
critical application #	3	
critical application rate	148.5 g/ha	
relevant applic. rate for v/d	148.126 g/ha	(reduced by drift loss of 0.252 %)
critical drift scenario	arable crops	

field-related parameters

crop interception	80%	select upper limit for critical application for v/d
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greenhouse-related parameters

		default	user input
greenhouse area (m²)	300	300	
greenhouse volume, VG (m³)	1000	1000	
air exchange rate, XR (VG/h)	24.5	24.5	

applied amount/greenhouse	4.44378 g
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deposition percentages

calculated values	dist. (m)	v/d (plants)	v/d (soil)	v/d (calc.)
	1	0.000%	0.000%	0.000%
	5	0.000%	0.000%	0.000%
	10	0.000%	0.000%	0.000%
	15	0.000%	0.000%	0.000%
	20	0.000%	0.000%	0.000%