REGISTRATION REPORT

Part B
Section 5: Environmental Fate

Detailed summary of the risk assessment

TRANSFORM (GF-2372)

500 g/Kg Sulfoxaflor

Southern Zone

Zonal Rapporteur Member State: France

CORE ASSESSMENT

Applicant: DOW AgroSciences

Date: October 2017

Table of Contents

IIIA 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Introduction

This document reviews the environmental fate and behaviour data relevant for the plant protection product GF-2372 containing the active substance sulfoxaflor.

Sulfoxaflor is a new active substance which have been approved under Regulation (EC) No 1107/2009, in the Commission Implementing Regulation (EU) 2015/1295. Ireland (Pesticide Registration and Control Division, PRCD) is the rapporteur Member State (RMS).

The EFSA peer review process was conducted and the EFSA conclusion was published in May 2014.

There were two representative formulations for the EU active approval submission. These were GF-2372 (500 g/kg WG) and GF-2626 (120 g/L SC).

This current submission is for one of these two formulations, GF-2372. This is the first submission for authorisation of plant protection products containing sulfoxaflor in EU Member States.

The review report SANTE/10665/2015 rev 2 of 29 May 2015 and the EFSA conclusions (EFSA Journal 2014; 12(5):3692)) for sulfoxaflor provides data on the active substance. Where appropriate, this document refers to the conclusions of the EFSA review report (EFSA Journal 2014; 12(5):3692) of sulfoxaflor. This will be where:

- the active substance data are relied upon in the risk assessment of the formulation;
- or when the EU review concluded that additional data/information should be considered at national registration.

This Part B document only reviews data (active substance or plant protection product) and additional information that has not previously been considered within the EU review process, as part of the active approval decision.

Details of the active substance, the active approval Regulation and the Commission Review Report are provided in Table #-1.

Table #-1: Details for the active substance

Active Substance	Approval Regulation	Commission Review Report	EFSA Scientific Report
Sulfoxaflor	Reg. (EU) 2015/1295 ,	SANTE/10665/2015 rev 2 of 29 May 2015	EFSA Journal 2014; 12(5):3692

The use pattern for sulfoxaflor evaluated in the EU assessment is illustrated in Table 9-1. The current submission for GF-2372 in Southern zone includes cereals, oil seed rape and cotton . The rates are increased (2 x 24 g a.s./ha) and an additional crop (oilseed rape) is also included. The current GAP is shown in Appendix 2 of this document and the critical GAP included in Table 9-1.

Table 9-1: GAP for sulfoxaflor that was evaluated at EU level as well as the critical GAP for uses of the product GF-2372 in the southern zone of the EU

Crop and/or situation	N or S	F/G or I	Application			Application Rate per Treatment	PHI
			Stage BBCH	Max. Number	Interval (d)	g a.s./ha max	(d)
GAP at EU level evaluation							
Fruiting vegetable – Tomato, Cherry tomato, pepper, aubergine, Cucurbit, cucumber, Melon, Water melon, courgette	N/S	F/G	BBCH 20 – 39 BBCH 40 - 89 Apr-Nov (for field) Through the year (for glasshouses)	1	-	24	≥ 1
Cereals (wheat, rye, barley, oat, triticale) [w,s]	N/S	F	BBCH 40 - 89 April - July	1	-	24	21
Cotton	N/S	F	BBCH 20 – 39 BBCH 40 - 89 May - Sept	1	-	24	14
Critical GAP for GF-2372 in the southern zone of the EU							
Rape seed	S	F	BBCH 10-87 Sept-dec/Apr-June	2 (1 in autumn + 1 spring or 2 in spring only)	21	24	28
Cotton seed	S	F	BBCH 20-87 (may-sept)	2	7	24	14
Cereals [w, s]	S	F	BBCH 12-87 Sept-dec/Apr-June	2 (1 in autumn + 1 spring or 2 in spring only)	21	24	21

F, G, I = Field, glasshouse, indoor

All exposure assessments in the current evaluation use the agreed endpoints as stated in the EFSA conclusion for sulfoxaflor.

Properties considered relevant in assessing the fate of sulfoxaflor and its metabolites are shown in Table 9-2. The relevant compartments of sulfoxaflor and its metabolites are given in Table 9-3.

Table 9-2: Agreed EU physical chemical properties used in the evaluation (EFSA Journal 2014; 12(5):3692)

Property	Sulfoxaflor
Molar mass [g/mol]	277.3
Molecular formula	$C_{10}H_{10}F_3N_3OS$
Solubility in water [mg/L] (20 °C)	568 (pH 7, purity: 99.7 %)
Vapour pressure (at 20 °C) [Pa]	1.4×10^{-6} (purity: 99.7 %)
Log P_{OW} (n-octanol/water partition coefficient)	log $P_{O/W}$ = 0.806 at 20 °C (pH 5) (99.7%) log $P_{O/W}$ = 0.802 at 20 °C (pH 7) (99.7%) log $P_{O/W}$ = 0.799 at 20 °C (pH 9) (99.7%)
Henry's Law Constant [Pa m^3/mol]	6.83×10^{-7} at 20 °C (pH 7)
Dissociation constant	Sulfoxaflor has no measurable ionisation constant within environmental relevant pH ranges (pH 2 to 10).

Table 9-3: Sulfoxaflor and its metabolites considered in the EU assessment to require risk assessment (EFSA Journal 2014;12(5):3692)

Code number/name	Compartment(s)
Sulfoxaflor	Soil, groundwater, surface water, sediment, air
X11719474	Soil, groundwater, surface water, sediment
X11519540	Soil, groundwater, surface water
X11579457	Groundwater

IIIA 9.1 Rate of degradation in soil (laboratory)

IIIA 9.1.1 Aerobic degradation of the preparation in soil

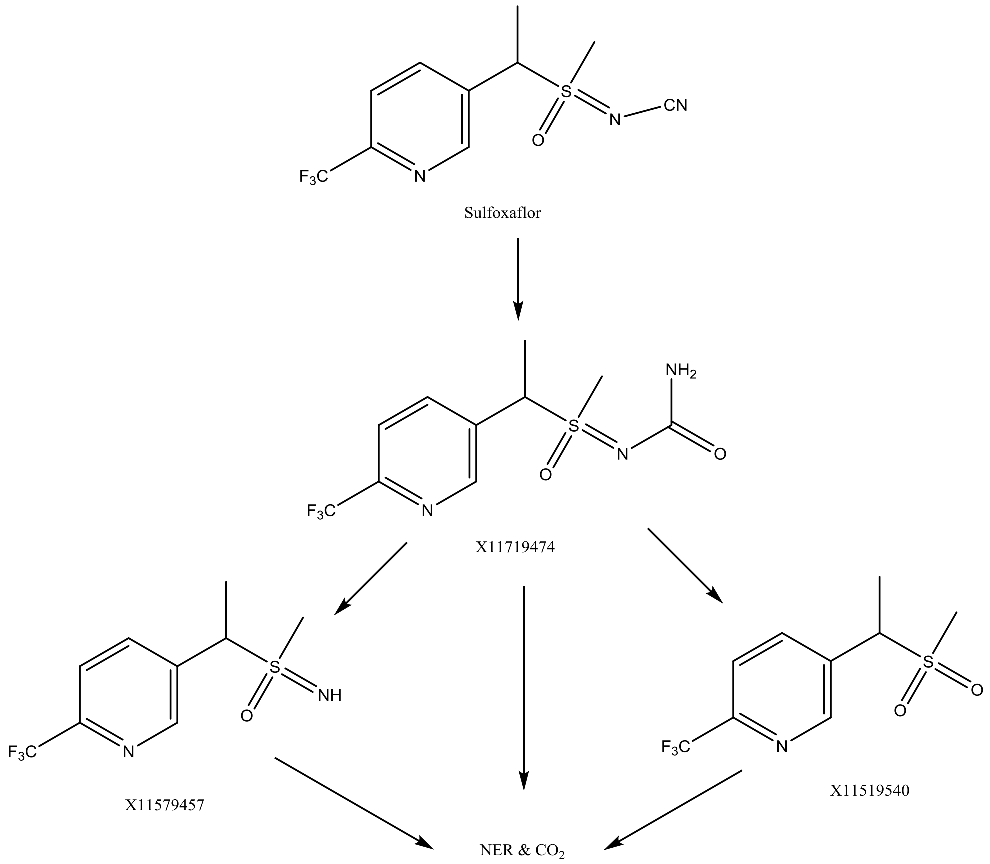
Route of degradation

The aerobic route of degradation of sulfoxaflor was investigated in laboratory and field conditions in a number of studies that were summarised in the DAR and EFSA conclusion (2014).

In soil under aerobic conditions the compound sulfoxaflor was rapidly and totally transformed to its primary major degradation product – X11719474 (96 to 99% AR after 24 hours), which in turn degraded to either X11519540 (max. occurrence in soil 12.2%, individual replicate) or X11579457 (max. occurrence in soil 9.2%, individual replicate). These two secondary metabolites were either mineralised (the determined overall level of mineralisation was up to ~32%) or incorporated into soil as the NER fraction (recorded in amounts up to 14.9%, individual replicate). The results of the examination of sulfoxaflor in sterilised aerobic soil showed that the whole degradation pathway leading from the parent compound to the terminal

degradation products – CO_2 (and other products of mineralisation) and the non-extractable residues was predominantly biologically-mediated.
The determined degradation pathway is shown below in figure 9.1-1.

Figure 9.1-1: The proposed metabolic pathway of sulfoxaflor in soil under aerobic conditions



Soil photolysis

Soil photolysis was demonstrated not to be a relevant degradation mechanism of sulfoxaflor.

Rates of degradation

The kinetic analysis of the data showed that sulfoxaflor was a very short-lived compound in soil with lab derived DT_{50} = 0.078 day (geomean, normalised) and DT_{90} = 0.26 day (geomean, normalised).
The degradation products of sulfoxaflor were much more persistent in soil and endpoints from laboratory studies are shown in Table 9-5 to Table 9-8.

Table 9.1.1-1: Sulfoxaflor aerobic rate of degradation in soil (laboratory studies) from EFSA Journal 2014;12(5):3692

Soil	Soil properties	Incubation conditions	Kinetic model	Kinetic parameters	Evaluation of the fit	Kinetic endpoints

Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [°C]*	*Moist. Cont. [% WHC]*		*Param.*	*Value*	*Visual fit*	*R^2*	*χ^2 % error*	*DT_{50} [days]*	*DT_{90} [days]*
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	SFO	*k*	8.5	Very good	1.00	0.8	0.082	0.27
Aberford	Sandy clay loam	7.3	6.7	20	40 (pF2)	SFO	*k*	15.6	Very good	1.00	1.9	0.044	0.15
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	SFO	*k*	16.9	Very good	1.00	1.9	0.041	0.14
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	SFO	*k*	2.7	Good	0.99	3.5	0.26	0.87
Geometric mean (n=4)												**0.078**	**0.26**

Table 9.1.1-2: X11719474 aerobic rate of degradation in soil (laboratory studies) from experiments where sulfoxaflor was the precursor dosed from EFSA Journal 2014;12(5):3692

Soil		**Soil properties**		**Incubation conditions**		**Kinetic model**	**Kinetic parameters**		**Evaluation of the fit**			**Kinetic endpoints**	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [°C]*	*Moist. Cont. [% WHC]*		*ff from parent*	*k value*	*Visual fit*	*R^2*	*χ^2 % error*	*DT_{50} [days]*	*DT_{90} [days]*
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	SFO	*0.98*	0.0025	Very good	0.984	3.5	281.95	936.61
Aberford	Sandy clay loam	7.3	6.7	20	40 (pF2)	SFO	*0.94*	0.0082	Very good	0.987	4.8	84.58	280.97
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	SFO	*0.944*	0.0019	Very good	0.996	1.3	370.38	1121.10
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	SFO	*0.996*	0.0025	Very good	0.986	3.0	274.27	911.10
Geometric mean (n=4)												**221.85**	**734.20**

Table 9.1.1-3: X11519540 aerobic rate of degradation in soil (laboratory studies where the metabolite was applied as test substance) from EFSA Journal 2014;12(5):3692

Soil		Soil properties		Incubation conditions			Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [°C]*	*Moist. Cont. [% WHC]*	Kinetic model	*param.*	*value*	*Visual fit*	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0022	Good	0.992	2.46	315.07	1046.63
Aberford	Sandy clay loam	7.3	6.7	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	$6.0\ E^{-4}$	Good	0.838	3.02	1155.24	3837.62
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	$6.1\ E^{-4}$	Good	0.938	1.79	1136.31	3774.73
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0070	Good	0.918	7.18	99.02	328.94
Geometric mean (n=4)												**449.86**	**1494.39**

Table 9.1.1-4: X11579457 aerobic rate of degradation in soil (laboratory studies where the metabolite was applied as test substance) from EFSA Journal 2014;12(5):3692

Soil		Soil properties		Incubation conditions			Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [°C]*	*Moist. Cont. [% WHC]*	Kinetic model	*param.*	*value*	*Visual fit**	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0022	G	0.973	1.03	315.07	1046.63
Aberford	Sandy clay loam	7.3	6.7	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0080	G	0.982	3.45	86.64	287.82
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	Pseudo-SFO (slow	k_2	0.0054	G	0.926	6.30	128.36	426.40

						phase of the HS)							
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0020	I	0.757	5.57	346.57	1151.29
Geometric mean (n=4)												**186.67**	**620.12**

* Following abbreviations were used: I – intermediate; G- good

IIIA 9.1.1 Anaerobic degradation of the preparation in soil

Under anaerobic conditions the transformation pathway of sulfoxaflor in soil was very similar, with the primary degradation product X11719474 forming in amounts up to 98% 4 days after flooding. However, unlike in aerobic soil, this compound was found to degrade under anaerobic conditions only through forming the NER. Neither X11519540 nor X11579457 were detected under anaerobic conditions. The level of mineralisation was very low, not surpassing 0.4%.

IIIA 9.2 Field studies

IIIA 9.2.1 Soil dissipation testing on a range of representative soils

In satisfactory field dissipation studies carried out at four sites (one each in Germany, northern France, Spain and Italy, spray application of sulfoxaflor at N and 2N rates to the soil surface on bare soil plots in May), sulfoxaflor exhibited low persistence and X11719474 exhibited moderate to high persistence.

In addition, satisfactory field dissipation studies for X11519540 were carried out at four sites, one each in Germany, northern France, Spain and Italy, (spray application of X11519540 to the soil surface on bare soil plots in April, May or July).

Field study DT_{50} values from the available field dissipation trials were accepted as being reasonable estimates of degradation for X11719474 and X11519540, after normalisation to FOCUS reference conditions (20°C and PF2 soil moisture), using the time step normalisation procedure in accordance with FOCUS (2006) kinetics guidance.

<u>**Active substance Sulfoxaflor**</u>

Best fit kinetic, persistence endpoint

Table 9.2.1-1: Sulfoxaflor aerobic rate of degradation in soil (field studies) from EFSA Journal 2014;12(5):3692

Trial	*Soil type (USDA classif.)*	Soil properties		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
		pH	***OC [%]***		***Param.***	***Value***	***Visual fit****	***R^2***	***χ^2 % error***	***DT_{50} [days]***	***DT_{90} [days]***
CEMS-3990A	Silt loam	5.9	1.2	Fit not found	---	---	---	---	---	---	---
CEMS-	Clay loam	7.1	2.2	SFO – stand	*k*	0.3665	I	0.6392	19.18	1.89	6.28

3990B				alone							
CEMS-3990C	Clay loam	7.4	0.8	Fit not found	---	---	---	---	---	---	---
CEMS-3990D	Loam	7.2	1.3	SFO – stand alone	*k*	0.2115	I	0.8357	16.85	3.28	10.88
CEMS-4012A	Silt loam	5.9	1.2	SFO – stand alone	*k*	0.4753	G	0.8740	26.65	1.46	4.84
CEMS-4012B	Clay loam	7.1	2.2	SFO – stand alone	*k*	0.0933	G	0.9958	4.21	7.43	24.68
CEMS-4012C	Clay loam	7.4	0.8	SFO – stand alone	*k*	0.1729	I	0.7470	17.50	4.01	13.32
CEMS-4012D	Loam	7.2	1.3	SFO – stand alone	*k*	0.2201	I	0.7636	17.98	3.15	10.46

* Following abbreviations were used: I – intermediate; G- good

Metabolite X11719474

Best fit kinetic, persistence endpoint

Table 9.2.1-2: X11719474 aerobic rate of degradation in soil (field studies) from experiments where sulfoxaflor was the precursor dosed from EFSA Journal 2014;12(5):3692

Trial	*Soil type (USDA classif.)*	Soil properties		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
		pH	*OC [%]*		*Param.*	*Value*	*Visual fit**	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
CEMS-3990A	Silt loam	5.9	1.2	DFOP – top-down approach	k_1	0.0803	G	0.9265	18.57	8.91	31.29
					k_2	0.0023				301.37†	1001.12†
					g	0.9777					
					Overall fit					8.91	750
CEMS-3990B	Clay loam	7.1	2.2	SFO – top-down	*k*	0.0364	G	0.8731	24.97	19.06	63.33
CEMS-3990C	Clay loam	7.4	0.8	DFOP – top-down approach	k_1	1.7119	VG	0.9876	12.51	0.43	1.68
					k_2	0.0053				130.78†	434.45†
					g	0.9531					
					Overall fit					0.43	180
CEMS-3990D	Loam	7.2	1.3	DFOP – top-down approach	k_1	0.6046	G	0.9451	23.50	1.15	3.87
					k_2	0.0018				385.08†	1279.21†
					g	0.9959					
					Overall fit					1.15	480
CEMS-4012A	Silt loam	5.9	1.2	DFOP – top-down approach	k_1	0.0794	G	0.9444	14.70	11.99	363.29
					k_2	0.0018				385.08†	1279.21†
					g	0.8074					
					Overall fit					11.99	550
CEMS-4012B	Clay loam	7.1	2.2	DFOP – top-down approach	k_1	0.1787	G	0.9599	15.40	5.47	227.62
					k_2	0.0031				223.60†	742.77†
					g	0.7958					
					Overall fit					5.47	295
CEMS-4012C	Clay loam	7.4	0.8	SFO – top-down	*k*	0.0071	G	0.9265	18.84	97.34	323.37
CEMS-4012D	Loam	7.2	1.3	DFOP – top-down approach	k_1	0.3707	VG	0.9969	6.15	1.93	6.80
					k_2	0.0040				173.29†	575.65†
					g	0.9779					
					Overall fit					1.93	410

* Following abbreviations were used: I – intermediate; G- good, VG – very good;
†The value for the *k2* representing the slow phase of the DFOP fit.

Modelling kinetic endpoint

Table 9.2.1-3: X11719474 aerobic rate of degradation in soil (field studies) from experiments where sulfoxaflor was the precursor dosed from EFSA Journal 2014;12(5):3692 - normalised to standard conditions of T = 20 0C and pF2 using Q10 = 2.58 and Walker factor = 0.7

Trial	Soil type (USDA classif.)	Soil properties		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
		pH	OC [%]		Param.	Value	Visual fit*	R^2	χ^2 % error	DT_{50} [days]	DT_{90} [days]
CEMS-3990A	Silt loam	5.9	1.2	SFO – top-down approach	k	0.0085	G	0.9472	12.47	81.15	269.58
CEMS-3990B	Clay loam	7.1	2.2	SFO – top-down approach	k	0.0497	I	0.9091	21.23	13.95	46.35
CEMS-3990C	Clay loam	7.4	0.8	SFO – refined top-down approach	k	0.0050	I	0.8832	24.11	138.16	458.97
CEMS-3990D	Loam	7.2	1.3	Fit not found	k	---	---	---	---	---	---
CEMS-4012A	Silt loam	5.9	1.2	SFO – fitted with parent	k	0.0090	I	0.6631	36.49	76.92	255.52
CEMS-4012B	Clay loam	7.1	2.2	SFO – refined top-down approach	k	0.0122	I	0.7543	21.47	56.86	188.90
CEMS-4012C	Clay loam	7.4	0.8	SFO – top-down approach	k	0.0048	I	0.8431	27.62	145.02	481.73
CEMS-4012D	Loam	7.2	1.3	SFO – refined top-down approach	k	0.0044	VG	0.9861	5.75	156.12	518.62
Geometric mean (n=7)										**76.61**	**254.50**

* Following abbreviations were used: I – intermediate; G- good, VG – very good

Metabolite X11519540

Modelling kinetic endpoint

Table 9.2.1-4: X11519540 aerobic rate of degradation in soil (field studies where the metabolite was applied as test substance) from EFSA Journal 2014;12(5):3692 - normalised to standard conditions of T = 20 ^{0}C and pF2 using Q10 = 2.58 and Walker factor = 0.7

Trial	Soil type (USDA classif.)	Soil properties		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
		pH	OC [%]		Param.	Value	Visual fit*	R^2	χ^2 % error	DT_{50} [days]	DT_{90} [days]
CEMS-3993A	Silt loam	5.3	0.95	SFO	k	0.02571	G	0.826	14.06	27.0	90.0
CEMS-3993B	Silt loam	6.65	0.76	SFO	k	0.01892	G	0.879	11.55	36.6	122.0
CEMS-3993C	Loam	7.61	0.58	SFO	k	0.007286	I	0.659	19.04	95.1	316.0
CEMS-3993E	Silty clay	7.63	0.63	SFO	k	0.0243	G	0.908	14.09	28.5	94.8
Geometric mean (n=4)										**40.5**	**135**

* Following abbreviations were used: I – intermediate; G- good

IIIA 9.2.2 Soil residue testing

IIIA 9.2.3 Soil accumulation testing

According to the EFSA conclusion, field accumulation studies indicated that neither sulfoxaflor nor metabolites X11519540 or X11579457 displayed a tendency for accumulation in soil as the results of the studies on soil accumulation at two European sites indicated that there was no accumulation throughout the study duration (5 years) in any of the trials. For X11719474, on the other hand, no clear accumulation pattern was observed throughout the study duration in any of the trials. It was therefore concluded that results of model calculation should be used.

IIIA 9.2.4 Aquatic (sediment) field dissipation

This is not an EC data requirement/not required by Regulation 1107/2009.

IIIA 9.2.5 Forestry field dissipation

This is not an EC data requirement/not required by Regulation 1107/2009.

Conclusions on Aerobic degradation rates

The values selected (EFSA, 2014) to be used in risk assessments are shown in Table 9.1-9.

Table 9.2.5-1: Soil endpoints for sulfoxaflor and its metabolites (EFSA Journal 2014;12(5):3692)

Compound	Worst case DT_{50} for PEC soil [days]	Geometric mean DT_{50} normalised at 20 ^{0}C and pF2 for PEC gw [days]	Maximum occurrence in soil [%]	Formation fraction
Sulfoxaflor	7.43 (field)	0.078 (lab)	---	-
X11719474	385.08 (field)	76.61 (field)	100	1
X11519540	1155.24 (lab)	40.5 (field)	12.2	0.5
X11579457	not required	186.67 (lab)	9.2	0.5

IIIA 9.3 Mobility of the plant protection product in soil

Batch adsorption / desorption in soil was investigated in 17 soils for sulfoxaflor and metabolite X11719474, in 6 soils for metabolite X11519540 and in 7 soils for metabolite X11579457. Summary results are presented in Tables 9.3-1 to 9.3-4. No dependence upon soil pH was observed for parent sulfoxaflor or either metabolites. Sulfoxaflor and metabolite X11719474 may be classified as very highly to highly mobile in soil and metabolites X11519540 and X11579457 may be classified as very highly mobile in soil. Table 9.3-5 summarises the selected soil adsorption endpoints for sulfoxaflor and its metabolites according to EFSA (2014).

Table 9.2.5-1: Summary of the soil adsorption coefficients for Sulfoxaflor (EFSA Journal 2014;12(5):3692)

Soil type (USDA classification)	pH	OC [%]	Distribution constants		Freundlich isotherm's parameters			
			Kd [mL/g]	Kdoc [mL/g]	Kf [mL/g]	Kfoc [mL/g]	1/n	R^2
Loamy sand	7.6	1.3	0.29	22.31	0.29	22	1.06	0.966
Loam	7.3	6.7	0.93	13.88	0.81	12	0.96	0.999
Silt loam	6.2	3.5	0.47	13.43	0.4	12	0.95	0.999
Sandy loam	7.4	1.2	0.32	26.67	0.3	25	1.02	0.997
Clay loam	5.9	1.8	0.66	36.67	0.56	31	0.96	1.000
Clay loam	6.9	1.2	0.61	50.83	0.57	47	0.99	1.000
Loam	6.3	1.1	0.63	57.27	0.54	49	0.96	1.000
Sandy loam	6.4	1	0.37	37	0.33	33	0.98	0.998
Sandy clay loam	7.4	1.3	0.45	34.62	0.4	31	0.97	0.999
Clay loam	7.8	1.2	0.37	30.83	0.35	30	1	0.996
Clay loam	7.8	1.7	0.43	25.29	0.34	20	0.95	0.993
Silt loam	6.3	1.1	0.31	28.18	0.26	24	0.93	0.998
Sand	6.3	0.3	0.25	83.33	0.16	54	0.89	0.964
Loamy sand	6.2	0.8	0.57	71.25	0.43	53	0.91	0.999
Clay	7.9	1.8	1.29	71.67	1.28	71	0.98	1.000
Clay loam	6.7	1.1	0.58	52.73	0.51	46	0.97	1.000
Loam	6.9	1.8	0.68	37.78	0.52	29	0.93	0.998
Arithmetic mean			0.54	40.81	0.47	**35**	**0.96**	0.995

Table 9.2.5-2: Summary of the soil adsorption coefficients for X11719474 (EFSA Journal 2014;12(5):3692)

Soil type (USDA classification)	pH	OC [%]	Distribution constants		Freundlich isotherm's parameters			
			Kd [mL/g]	Kdoc [mL/g]	Kf [mL/g]	Kfoc [mL/g]	1/n	R^2
Loamy sand	7.6	1.3	0.2	15.38	0.18	14	1.03	0.963
Loam	7.3	6.7	0.5	7.46	0.47	7	1.00	0.999
Silt loam	6.2	3.5	0.29	8.29	0.29	8	1.03	0.997
Sandy loam	7.4	1.2	0.26	21.67	0.21	18	0.94	0.985
Clay loam	5.9	1.8	0.52	28.89	0.44	24	0.99	0.997
Clay loam	6.9	1.2	0.51	42.5	0.48	40	0.99	0.999
Loam	6.3	1.1	0.64	58.18	0.55	50	0.98	0.999
Sandy loam	6.4	1	0.24	24	0.21	21	1.01	0.992
Sandy clay loam	7.4	1.3	0.44	33.85	0.41	31	1.00	0.997
Clay loam	7.8	1.2	0.27	22.5	0.25	21	0.98	0.996
Clay loam	7.8	1.7	0.31	18.24	0.25	14	0.95	0.992
Silt loam	6.3	1.1	0.24	21.82	0.19	18	0.95	0.988
Sand	6.3	0.3	0.23	76.67	0.22	74	1.03	0.992
Loamy sand	6.2	0.8	0.28	35	0.24	30	0.98	0.996
Clay	7.9	1.8	1.32	73.33	1.24	69	1.00	1.000
Clay loam	6.7	1.1	0.54	49.09	0.49	45	0.99	1.000
Loam	6.9	1.8	0.44	24.44	0.41	23	1.03	0.994
Arithmetic mean			0.42	33.02	0.38	**30**	**0.99**	0.992

Table 9.2.5-3: Summary of the soil adsorption coefficients for X11519540 (EFSA Journal 2014;12(5):3692)

Soil type (USDA classification)	pH	OC [%]	Distribution constants		Freundlich isotherm's parameters			
			Kd [mL/g]	Kdoc [mL/g]	Kf [mL/g]	Kfoc [mL/g]	1/n	R^2
Loamy sand	7.6	1.3	0.04	3	0.01	1	1.35	0.856
Loam	7.3	6.7	0.28	4	0.39	6	0.79	0.825
Silt loam	6.2	3.5	0.2	5	0.22	6	0.96	0.976
Clay loam	5.9	1.8	0.31	17	0.36	20	0.92	0.931
Clay loam	6.9	1.2	0.26	22	0.29	24	1.01	0.995
Loam	6.3	1.1	0.31	29	0.28	25	1.04	0.993
Arithmetic mean			0.23	13.3	0.26	**14**	**1.01**	0.929

Table 9.2.5-4: Summary of the soil adsorption coefficients for X11579457 (EFSA Journal 2014;12(5):3692)

Soil type (USDA classification)	pH	OC [%]	Distribution constants		Freundlich isotherm's parameters			
			Kd [mL/g]	Kdoc [mL/g]	Kf [mL/g]	Kfoc [mL/g]	1/n	R^2
Loamy sand	7.6	1.3	0.10	8	0.15	11	0.87	0.905
Loam	7.3	6.7	0.14	2	0.13	2	1.02	0.985
Silt loam	6.2	3.5	0.08	2	0.34	10	0.55	0.907
Clay loam	5.9	1.8	0.21	12	0.79	44	0.43	0.867
Clay loam	6.9	1.2	0.21	18	0.27	23	0.91	0.994
Loam	6.3	1.1	0.26	22	0.28	26	0.97	0.99
Sandy loam	6.4	1.0	0.32	32	0.35	35	0.97	0.996
Arithmetic mean			0.19	14	0.33	**22**	**0.82**	0.949

Table 9.2.5-5: Soil adsorption endpoints for sulfoxaflor and its metabolites

Compound	Arithmetic mean Kfoc [mL/g]	Arithmetic mean 1/n	pH dependence
Sulfoxaflor	35	0.96	No
X11719474	30	0.99	No
X11519540	14	1.01	No
X11579457	22	0.82	No

IIIA 9.3.1 Column leaching

Not required. Sufficient information is available from the sorption studies on the active substance and the metabolites.

IIIA 9.3.2 Lysimeter studies

Not required. Sufficient information is available from the sorption studies and simulation modelling (see point IIIA 9.6) on the active substance and metabolites to predict leaching concentrations.

IIIA 9.3.3 Field leaching studies

Not required. Sufficient information is available from the sorption studies and simulation modelling (see point IIIA 9.6) on the active substance and metabolites to predict leaching concentrations.

IIIA 9.3.4 Volatility – laboratory study

Not required according to Regulation 1107/2009.

IIIA 9.3.5 Volatility – field study

Not required according to Regulation 1107/2009.

IIIA 9.4 Predicted environmental concentrations in soil (PECs) for the active substance

PEC_{soil} values were calculated considering standard scenario assumptions (5 cm soil depth and bulk density of 1.5 g/cm^3) and interception determined following FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.1 (Dec. 2012)). The worst case DT_{50} was used as described in Table 9.4-1. As the compound is not persistent, an accumulated PEC_{soil} ($PEC_{soil,accu}$) is not required.

The Table 9.4-1 below summarised the soil endpoint for sulfoxaflor according to EFSA Journal 2014;12(5):3692.

Table 9.4-1: Soil endpoints for sulfoxaflor

Compound	Worst case DT_{50} for PEC soil [days]
Sulfoxaflor	7.43 (field)

IIIA 9.4.1 Initial PECs values

PEC_{soil} values were calculated using FOCUS guidance[1].

In accordance with the GAP (Table 9.4.1-1) application to cereals, oilseed rape and cotton are considered for the calculations.

Table 9.4.1–1: Table of intended uses of GF-2372

Crop	Growth stage	Application rate (interval)	Interception (FOCUS, 2012)	Amount reaching soil
Cereals [w, s]	BBCH 12-29 + 30-87	2 x 24 g/ha (21 days)	25% - 1st application 50% - 2nd application	18 g/ha - 1st application 12 g/ha - 2nd application
Oilseed rape [w, s]	BBCH 10-29 + 30-87	2 x 24 g/ha (21 days)	40% - 1st application 80% - 2nd application	14.4 g/ha - 1st application 4.8 g/ha - 2nd application
Cotton seed	BBCH 20-87	2 x 24 g/ha (7 days)	60% - 1st application 60% - 2nd application	9.6 g/ha - 1st application 9.6 g/ha - 2nd application

Calculated PEC_{soil} values for the proposed uses are presented in Table 9.4.1-2.

[1] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

Table 9.4.1–1: Summary of PEC_{soil} values for sulfoxaflor following application to cereals, oilseed rape and cotton

Crop	Cereals	Oilseed rape	Cotton
Days after final application	Actual Initial PEC_{soil} (mg/kg)	Actual Initial PEC_{soil} (mg/kg)	Actual Initial PEC_{soil} (mg/kg)
0	0.019	0.009	0.019

Modelling Comments: IIIA 9.4.1	PECsoil provided by applicant were verified by zRMS and are validated.
Agreed PECsoil (active substance): IIIA 9.4.1	Worst-case Actual **PECsoil = 0.019 mg/kg** can be used to cover all uses.

IIIA 9.4.2 Short-term PECs values (1-4 days after last application)

Refer to point IIIA 9.4.1 above.

IIIA 9.4.3 Long-term PECs values (from 7-100 days after last application)

Refer to point IIIA 9.4.1 above.

IIIA 9.5 Predicted environmental concentrations in soil (PECs) for major metabolites

Overall summary

PEC_{soil} values for metabolites X11719474 and X11519540 were calculated considering standard scenario assumptions (5 cm soil depth and bulk density of 1.5 g/cm^3) and interception determined following FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.1 (Dec. 2012)).

The worst case DT_{50} were used as described in Table 9.5-1. As all metabolites are persistent if the worst DT_{50} are taken into account, accumulated PEC_{soil} ($PEC_{soil,accu}$) are required. These have been calculated based on plateau concentration for mixing over 20 cm plus a peak single season's PEC_{soil} based on mixing over 5 cm.

Table 9.5-1: Soil endpoints for sulfoxaflor metabolites according to EFSA Journal 2014;12(5):3692

Compound	Molecular weight [g/mol]	Worst case DT_{50} for PEC soil [days]	Maximum occurence in soil [%]
X11719474	295.3	385.08	100
X11519540	253.2	1155.24	12.2

Table 9.5-2 summarises the agronomic input parameters used for modelling. Correction for molecular weight and maximum occurence in soil were used to adjust the application rate and it was assumed that there was no degradation of the metabolites between applications.

Table 9.5-2: Agronomic input used for the simulations

Compound	Crop	Application Rate reaching soil for the parent (g a.s./ha)	Correction factor (MW and % occurence in soil)	Application Rate reaching soil (g a.s./ha)
X11719474	Cereals	18 - 1st application 12 - 2nd application (21 days interval)	1.06	19.08 - 1st application 12.72 - 2nd application (21 days interval)
	Oilseed rape	14.4 g/ha - 1st application 4.8 g/ha - 2nd application (21 days interval)	1.06	15.26 g/ha - 1st application 5.09 g/ha - 2nd application (21 days interval)
	Cotton seed	9.6 g/ha - 1st application 9.6 g/ha - 2nd application (7 days interval)	1.06	10.18 g/ha - 1st application 10.18 g/ha - 2nd application (7 days interval)
X11519540	Cereals	18 - 1st application 12 - 2nd application (21 days interval)	0.11	1.98 - 1st application 1.32 - 2nd application (21 days interval)
	Oilseed rape	14.4 g/ha - 1st application 4.8 g/ha - 2nd application (21 days interval)	0.11	1.58 g/ha - 1st application 0.53 g/ha - 2nd application (21 days interval)
	Cotton seed	9.6 g/ha - 1st application 9.6 g/ha - 2nd application (7 days interval)	0.11	1.06 g/ha - 1st application 1.06 g/ha - 2nd application (7 days interval)

Calculated PEC_{soil} values for the proposed uses are presented in Tables 9.5.1-1 and 9.5.1-2.

IIIA 9.5.1 Initial PECs values

Table 9.5.1–1: Summary of PEC_{soil} values for X11719474 following application of sulfoxaflor to cereals, oilseed rape and cotton

Crop	Cereals	Oilseed rape	Cotton
Days after final application	**Actual PEC_{soil} (mg/kg)**	**Actual PEC_{soil} (mg/kg)**	**Actual PEC_{soil} (mg/kg)**
0	0.041	0.026	0.027
PECsoil, accu	0.053	0.035	0.035

Table 9.5.1–2: Summary of PEC_{soil} values for X11519540 following application of sulfoxaflor to cereals, oilseed rape and cotton

Crop	Cereals	Oilseed rape	Cotton
Days after final application	**Actual PEC_{soil} (mg/kg)**	**Actual PEC_{soil} (mg/kg)**	**Actual PEC_{soil} (mg/kg)**
0	0.004	0.003	0.003
PECsoil, accu	0.008	0.005	0.005

Modelling Comments: IIIA 9.5.1	PECsoil for metabolites provided by applicant were verified by zRMS and are validated.
Agreed PECsoil (metabolites): IIIA 9.5.1	The following PECplateau can be used to cover all uses: X11719474 : **PECsoil, accu** = **0.053 mg/kg** X11519540 : **PECsoil, accu = 0.008 mg/kg**

IIIA 9.5.2 Short-term PECs values (1-4 days after last application)

Refer to point IIIA 9.5.1 above.

IIIA 9.5.3 Long-term PECs values (from 7-100 days after last application)

Refer to point IIIA 9.5.1 above.

IIIA 9.6 Predicted environmental concentrations in groundwater (PECgw)

IIIA 9.6.1 Active substance

Report:	IIIA1 9.6.1/01, Jarvis, T. and Montesano V., 2014a
Title:	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2372) and its metabolites in groundwater using the FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 ground water scenarios.
Document No:	Exponent International Ltd. Report No.: 1402547.UK0-3366
Guidelines:	FOCUS (2001, 2009, 2012).
GLP	No. Not required

I. MATERIAL AND METHODS

Groundwater modelling of sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 has been undertaken using the relevant FOCUS groundwater scenarios and the FOCUS PEARL 4.4.4 and PELMO 5.5.3 models. The modelling undertaken was based on the GAP requested for product registration of GF-2372 in the southern zone of the EU for uses on winter and spring cereals, oil seed rape and cotton.

In accordance with the GAP, the agronomic parameters used as input for these simulations were therefore as follows:

Crop: Winter cereals
Application: 2 x 24 g as/ha
Crop Interception: 25% (first application) and 50% (second application)
Application Timing: First application: emergence + 1 week
Second application: 1st March

Crop: Spring cereals
Application Rate: 2 x 24 g as/ha (21 days interval)
Crop Interception: 25% (first application) and 50% (second application)
Application Timing: First application: emergence + 1 week
Second application: emergence + 4 week

Crop: Winter oilseed rape
Application: 2 x 24 g as/ha
Crop Interception: 40% (first application) and 80% (second application)
Application Timing: First application: emergence + 1 week
Second application: 1st April

Crop: Summer oilseed rape
Application Rate: 2 x 24 g as/ha (21 days interval)
Crop Interception: 40% (first application) and 80% (second application)

Application Timing: First application: emergence + 1 week
Second application: emergence + 4 week

Crop: Cotton
Application Rate: 2 x 24 g as/ha (7 days interval)
Crop Interception: 60%
Application Timing: First application: emergence + 3 weeks
Second application: emergence + 4 week

The actual application dates used in the simulations are summarised in Table 9.6.1-1. The simulations for spring cereals and spring oilseed rape are considered to also cover the situation in winter cereals and winter oilseed rape, respectively, where both applications occur in the spring.

The interception values were taken from Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.1 (Dec. 2012).

Table 9.6.1-1: Actual application dates used for the application on the different crops

Crop	Winter cereal	Spring cereal	Winter oilseed rape	Summer oilseed rape	Cotton
Application	Autumn/Spring	Spring	Autumn/Spring	Spring	
Chateaudun	2 Nov/1 Mar	17 Mar/7 Apr	14 Sep/1 Apr	--	--
Hamburg	8 Nov/1 Mar	8 Apr/29 Apr	9 Sep/1 Apr	--	--
Jokioinen	27 Sep/1 Mar	25 May/15 Jun	--	27 May/17 Jun	--
Kremsmunster	12 Nov/1 Mar	8 Apr/29 Apr	9 Sep/1 Apr	--	--
Okehampton	24 Oct/1 Mar	8 Apr/29 Apr	21 Aug/1 Apr	6 Apr/27 Apr	--
Piacenza	8 Dec/1 Mar	--	12 Oct/1 Apr	--	--
Porto	7 Dec/1 Mar	17 Mar/7 Apr	14 Sep/1 Apr	29 Mar/19 Apr	--
Sevilla	7 Dec/1 Mar	--	--	--	26 Apr/3 May
Thiva	7 Dec/1 Mar	--	--	--	5 Jun/12 Jun

The active substance and metabolite endpoints used in the assessments are summarised in Table 9.6.1-2.

Table 9.6.1-2: Sulfoxaflor and metabolites input parameters used for the simulations

Parameter	Sulfoxaflor	X11719474	X11519540	X11579457
Molecular mass [g/mol]	277.3	295.3	253.2	252.3
Vapour pressure [Pa] at 20 ºC	$1.4x10^{-6}$	$1.4x10^{-6}$	$1.4x10^{-6}$	$1.4x10^{-6}$
Solubility in water [mg/L] at 20 ºC	568	568	568	568
Henry's law constant [$Pa.m^3.mol^{-1}$] at 20 ºC	$6.83x10^{-7}$	n.r	n.r.	n.r.
Koc /Kom [mL/g], arith. mean	35/20.3	30/17.4	14/8.12	22/12.8
Freundlich exponent, arith. mean	0.96	0.99	1.01	0.82
DT_{50} soil [d]	0.1 (lab, geometric mean at 20°C and pF2)	76.6 (field – geom. mean normalised to pF2 and 20°C)	40.5(field – geom. mean normalised to pF2 and 20°C)	186.7(lab – geom. mean normalised to pF2 and 20°C)
Crop uptake factor[1]	0	0	0	0
Formation fraction	--	1 (from parent)	0.5 (from X11719474)	0.5 (from X11719474)

[1] Conservative value; n.r. = not required

II. RESULTS AND DISCUSSION

PECgw values from FOCUS PELMO 5.5.3 and PEARL 4.4.4 for sulfoxaflor and its metabolites are shown in Tables 9.6.1-3 to 9.6.1-7.

Table 9.6.1-3: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to winter cereal (1 application in autumn + 1 application in spring)

Model	PEARL 4.4.4			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	3.015	1.371	3.372
HAMBURG	< 0.001	4.717	1.915	2.681
JOKIOINEN	< 0.001	4.972	2.915	3.084
KREMSMUENSTER	< 0.001	3.053	1.118	1.763
OKEHAMPTON	< 0.001	3.484	1.050	1.401
PIACENZA	< 0.001	2.367	1.008	2.430
PORTO	< 0.001	2.315	0.991	1.583
SEVILLA	< 0.001	0.569	0.483	0.990
THIVA	< 0.001	2.567	1.409	4.807
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	2.943	1.326	3.387
HAMBURG	< 0.001	5.179	1.856	2.445
JOKIOINEN	< 0.001	5.162	2.340	2.426
KREMSMUENSTER	< 0.001	3.820	1.390	2.164
OKEHAMPTON	< 0.001	3.699	1.076	1.444
PIACENZA	< 0.001	3.339	1.401	3.052
PORTO	< 0.001	2.402	0.971	1.381
SEVILLA	< 0.001	0.802	0.489	1.778
THIVA	< 0.001	1.871	1.007	3.260

Table 9.6.1-4: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to spring cereal (2 applications in spring)

Model	PEARL 4.4.4			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	1.934	1.078	2.634
HAMBURG	< 0.001	5.087	2.424	3.411
JOKIOINEN	< 0.001	3.666	2.218	2.311
KREMSMUENSTER	< 0.001	3.135	1.209	2.005
OKEHAMPTON	< 0.001	2.710	1.027	1.511
PORTO	< 0.001	1.516	0.733	1.269
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	1.652	0.901	2.390
HAMBURG	< 0.001	3.622	1.690	2.542
JOKIOINEN	< 0.001	3.383	1.890	2.095
KREMSMUENSTER	< 0.001	3.113	1.292	2.119
OKEHAMPTON	< 0.001	2.627	0.950	1.369
PORTO	< 0.001	1.690	0.763	1.223

Table 9.6.1-5: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to winter oilseed rape (1 application in autumn + 1 application in spring)

Model	PEARL 4.4.4			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	2.391	1.284	3.225
HAMBURG	< 0.001	3.066	1.229	1.646
KREMSMUENSTER	< 0.001	1.957	0.732	1.018
OKEHAMPTON	< 0.001	1.889	0.618	0.779
PIACENZA	< 0.001	1.491	0.552	1.197
PORTO	< 0.001	1.911	0.741	0.976
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	2.353	1.156	2.667
HAMBURG	< 0.001	3.371	1.154	1.478
KREMSMUENSTER	< 0.001	2.357	0.873	1.274
OKEHAMPTON	< 0.001	2.117	0.674	0.836
PIACENZA	< 0.001	1.915	0.709	1.444
PORTO	< 0.001	1.882	0.669	0.836

Table 9.6.1-6: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to summer oilseed rape (2 applications in spring)

Model	PEARL 4.4.4			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
JOKIOINEN	< 0.001	2.143	1.362	1.329
OKEHAMPTON	< 0.001	1.581	0.609	0.891
PORTO	< 0.001	0.893	0.500	0.762
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
JOKIOINEN	< 0.001	2.131	1.198	1.306
OKEHAMPTON	< 0.001	1.671	0.611	0.845
PORTO	< 0.001	1.146	0.535	0.755

Table 9.6.1-7: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to cotton (2 applications)

Model	PEARL 4.4.4			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
SEVILLA	< 0.001	1.086	0.667	1.890
THIVA	< 0.001	1.531	0.814	2.347
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**

SEVILLA	< 0.001	1.103	0.642	1.899
THIVA	< 0.001	1.292	0.715	2.024

Modelling Comments: IIIA 9.6.1	The PECgw provided by applicant could not be verified in detail for each scenario by zRMS since the input raw modelling files were not available. However, the same calculations were provided for Central zone and have been checked or reproduced by zRMS Poland. Calculations provided are thus considered acceptable, but they are not totally covering the intended uses; indeed, double application in spring is simulated on the crops “spring cereals” and “summer oilseed rape” although it should be performed on the crops “winter cereals” and “winter oilseed rape” to adequately cover the GAPs. Central zRMS Poland carried out the missing spring simulation on winter cereals (2 x 24 g/ha, 21 days interval, from 15th March or 1st April, 0% crop interception). The maximum PECgw for metabolites X11719474, X11519540, X11579457 were 6.54 µg/L, 3.05 µg/L and 6.74 µg/L respectively. Central zRMS Poland also carried out additional simulation for two winter applications on winter cereals (2 x 24g/ha, 2 days after emergence). The maximum PECgw for metabolites X11719474, X11519540, X11579457 were 8.38, 3.74 and 5.92 µg/L respectively. As worst-case, those results are considered covering all the intended use of the preparation GF-2372). No additional calculations are available for oilseed rape. However, based on the results of simulation on winter cereals, and based on results of simulation of autumn + spring application on winter oilseed rape, it is expected that the PECgw after double spring application will be in the same order of magnitude. As indicated above, the worst-case PECgw obtained by central zRMS for double winter application on winter cereals are considered covering all intended uses. For cotton, PECgw modelling by applicant was carried out at the beginning of the application period only. However, later application would have considered a higher crop interception value. It is thus considered that the calculations provided are covering the whole potential application period.
Agreed PECgw (active substance): IIIA 9.6.1	**CONCLUSION** PECgw for active substance are <0.001 µg/L for all scenarios and all intended uses. PECgw for metabolites X11719474, X11519540 and X11579457 are > 0.1 µg/L in all scenarios and often >0.75 µg/L. An assessement of the relevance according to SANCO 221/2000 of these three metabolites is available in section 8. In this document a consumer risk assessment is performed based on the worst-case PECgw of 8.38, 3.74 and 5.92 µg/L respectively for metabolites X11719474, X11519540 and X11579457 covering all the intended uses.

	⇨ considering that the consumer risk assessment is based on risk envelope approach and results in a significant safety margin, it is considered **that no unacceptable risk of ground water contamination is expected for the intended uses**.

IIIA 9.6.2 Relevant (major) metabolites

Please refer to Point IIIA 9.6.1.

IIIA 9.6.3 Additional field testing

No data, not required.

IIIA 9.6.4 Information on impact on water treatment procedures

No data, not required.

IIIA 9.7 Predicted environmental concentrations in surface water (PECsw) for the active substance

In laboratory incubations in dark aerobic natural sediment water systems, sulfoxaflor exhibited moderate to medium persistence, forming the major metabolite X11719474 (max. 66% AR in total system at 88 days, max. 48 % AR in water at 76 days and 30 % AR in sediment at 88 days, as sum of isomers), with no decline of X11719474 being apparent in the experiments. Adsorption of sulfoxaflor to sediment reached a maximum o 40% AR at day 15. The unextractable sediment fraction (not extracted by acidified acetonitrile) was a sink for the pyridine ring ^{14}C radiolabel, accounting for 7 – 24 % AR at study end (103 days). Mineralisation of this radiolabel accounted for only 0.6 – 1.6 % AR at the end of the study.

Sulfoxaflor is stable to hydrolysis. The rate of decline of sulfoxaflor in a laboratory sterile aqueous photolysis experiment was slow relative to that which occurred in the aerobic sediment water incubations.

Table 9.3.5-1: Summay of persistence and modelling degradation rate for sulfoxaflor in water-sediment system, from EFSA Journal 2014;12(5):3692

Persistence endpoint									
System	**Whole system**			**Water phase**			**Sediment**		
	DT_{50}	**DT_{90}**	**model**	**DT_{50}**	**DT_{90}**	**model**	**DT_{50}**	**DT_{90}**	**model**
Sand-sediment system	88.86	295.20	SFO	64.18	213.20	SFO	101.93	388.62	SFO
Silt-loam sediment system	36.67	121.83	SFO	11	63	DFOP	46.21	153.51	SFO
Modelling endpoint									
System	**Whole system**			**Water phase**			**Sediment**		

	DT_{50}	**DT_{90}**	**model**	**DT_{50}**	**DT_{90}**	**model**	**DT_{50}**	**DT_{90}**	**model**
Sand-sediment system	88.86	295.20	SFO	n.d			101.93	388.62	SFO
Silt loam-sediment system	36.67	121.83	SFO	n.d			46.21	153.51	SFO
Geomean	**57.08**	**189.63**		n.d.			**68.63**	**244.25**	

Table 9.7-1 below summarises the appropriate endpoints for sulfoxaflor and its metabolites according to EFSA Journal 2014;12(5):3692 to be used in PECsw calculations

Table 9.3.5-2: Degradation kinetic endpoints for PECsw modelling of sulfoxaflor and its metabolites in water/sediment system (EFSA, 2014)

Compound	**DT_{50} water [days]**	**DT_{50} sed [days]**	**DT_{50} whole system [days]**	**Maximum occurence in water/sed system [%]**
Sulfoxaflor	57.08	68.63	57.08	---
X11719474	1000*	1000*	1000*	70.9†
X11519540	1000*	1000*	1000*	0.0001

* Conservative value
† based on single replicate

Predicted environmental concentrations values for the formulation

Single application was considered as the formulation is not considered to be maintained over time and hence will not remain present for any subsequent applications. Calculation of the PEC values for the formulation arising from the drift loading into surface water (same individual application rate for cereals, oilseed rape and cotton) was performed using the FOCUS drift calculator in SWASH at 1 m. The results are in Table 9.7-2 below.

Parameters used in the Drift calculator:

Application rate: 1 x 48 g GF-2372/ ha
Crop: Cotton / Cereals / oilseed rape
Drift: at 1 m

Table 9.3-2: Drift PEC values from the formulation at 1 m

Waterbody	**PEC sw (µg/L)**
Ditch	0.3084
Pond	0.0158
Stream	0.3084

Modelling Comments: IIIA 9.7	PECsw for the formulation were verified by zRMS and are validated.
Agreed PECsw: IIIA 9.7	Maximum PECsw for the formulation of 0.3084 µg/L is used for risk assessement in section 6.

Predicted environmental concentrations values for the active substance and its metabolites

IIIA 9.7.1 Initial PECsw value for static water bodies

Report:	IIIA1 9.7.1/01, Jarvis, T. and Montesano V., 2014b
Title:	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2372) and its Metabolites in Surface Water using the FOCUS Surface Water Scenarios.
Document No:	Exponent International Ltd. Report No.: 1402547.UK0-7910
Guidelines:	FOCUS (2001, 2012).
GLP	No. Not required

I. MATERIAL AND METHODS

Surface water calculations of sulfoxaflor have been undertaken using the FOCUS surface water scenarios Steps 1 & 2 version 2.1. The modelling performed in this exercise was based on the GAP requested for product registration of GF-2372 in the southern zone of the EU for uses on winter and spring cereals, oilseed rape and cotton.

In accordance with the GAP, the agronomic parameters used as input for these simulations were therefore as follows:

Step 1 – 2

Crop: Winter cereals and Spring cereals
Application Rate: 2 x 24 g as/ha
Interval: 21 days
Crop Interception: Minimal crop cover
Application Timing: NEU/SEU, Mar-May

Crop: Winter oilseed rape and Summer oilseed rape
Application Rate: 2 x 24 g as/ha
Interval: 21 days
Crop Interception: Average crop cover
Application Timing: NEU/SEU, Mar-May

Crop: Cotton
Application Rate: 2 x 24 g as/ha
Interval: 7 days
Crop Interception: Average crop cover
Application Timing: NEU/SEU, Mar-May

Sulfoxaflor endpoints used in the assessments are summarised in Table 9.7.1-2.

Table 9.7.1-2: Sulfoxaflor input parameters used for the simulations

Parameter	Sulfoxaflor
Molecular mass [g/mol]	277.3
Solubility in water [mg/L] at 20 °C	568
Koc [mL/g], arith. mean	35
DT_{50} soil [d] lab, geometric mean at 20°C and pF2	0.078 (lab. – in accordance with FOCUS SFO)
DT_{50} water [days]	57.08
DT_{50} sed [days]	68.63
DT_{50} whole system [days]	57.08

II. RESULTS AND DISCUSSION

Summary of the Step 1 & 2 maximum PECs values for sulfoxaflor can be seen in Table 9.7.1-3.

Table 9.7.1-3: Maximum Step 1 & 2 PECsw and PECsed values for Sulfoxaflor

Crop	Step	Region/ season application	Sulfoxaflor	
			PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Winter* cereal Spring cereal	1	---	15.73	5.43
	2	NEU, Mar – May	0.34 (0.22)	0.11 (0.07)
		SEU, Mar – May	0.34 (0.22)	0.11 (0.07)
Winter oilseed rape* Spring oilseed rape	1	---	15.73	5.43
	2	NEU, Mar – May	0.34 (0.22)	0.11 (0.07)
		SEU, Mar – May	0.34 (0.22)	0.11 (0.07)
Cotton	1	---	15.73	5.43
	2	NEU, Mar – May	0.37 (0.22)	0.12 (0.07)
		SEU, Mar – May	0.37 (0.22)	0.12 (0.07)

Values in brackets are for respective single application
* For winter cereals and winter oilseed rape, the PECs values for respective single application in the Oct-Feb period in the NEU and SEU are the same as in brackets for Mar-May period in the NEU and SEU.

Modelling Comments: IIIA 9.7.1	STEP 1-2 PECsw for sulfoxaflor were verified by zRMS and are validated.
Agreed PECsw (active substance): IIIA 9.7.1	Maximum PECsw for sulfoxaflor reported in Table 9.7.1-3 are used for risk assessement in section 6.

IIIA 9.7.2 Initial PECsw value for slow moving water bodies

Refer to point IIIA 9.7.1 above.

IIIA 9.7.3 Short-term PECsw values for static water bodies (1-4 days after last application)

Refer to point IIIA 9.7.1 above.

IIIA 9.7.4 Short-term PECsw values for slow moving water bodies (1-4 days after last application)

Refer to point IIIA 9.7.1 above.

IIIA 9.7.5 Long-term PECsw values for static water bodies (7-42 days after last application)

Refer to point IIIA 9.7.1 above.

IIIA 9.7.6 Long-term PECsw values for slow moving water bodies (7-42 days after last application)

Refer to point IIIA 9.7.1 above.

IIIA 9.8 Predicted environmental concentrations in surface water (PECsw) for metabolites

IIIA 9.8.1 Initial PECsw value for static water bodies

Report:	IIIA1 9.7.1/01, Jarvis, T. and Montesano V., 2014b
Title:	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2372) and its Metabolites in Surface Water using the FOCUS Surface Water Scenarios.
Document No:	Exponent International Ltd. Report No.: 1402547.UK0-7910
Guidelines:	FOCUS (2001, 2012).
GLP	No. Not required

I. MATERIAL AND METHODS

Surface water calculations of sulfoxaflor metabolites have been undertaken using the FOCUS surface water scenarios Steps 1 & 2 version 2.1. The modelling performed in this exercise was based on the GAP requested for product registration of GF-2372 in the southern zone of the EU for uses on winter and spring cereals, oilseed rape and cotton.

Calculations were performed using the same application schemes as for parent.

Metabolites endpoints used in the assessments are summarised in Table 9.8.1-1.

Table 9.8.1-1: X11719474 and X11519540, input parameters used for the simulations

Parameter	X11719474	X11519540
Molecular mass [g/mol]	295.3	253.24
Solubility in water [mg/L] at 20 °C	8090	1000
Koc [mL/g], arith. mean	30	14
DT_{50} soil [d] lab, geometric mean at 20°C and pF2	76.61 (field – in accordance with FOCUS SFO)	40.5 (field – in accordance with FOCUS SFO)
DT_{50} water [days]	1000*	1000*
DT_{50} sed [days]	1000*	1000*
DT_{50} whole system [days]	1000*	1000*
% formed in soil	100	12.2
% formed in water/sed system	70.9	0.0001

n.r. = not required
* default value

II. RESULTS AND DISCUSSION

A summary of the Step 1 & 2 maximum PECsw values for sulfoxaflor metabolites can be seen in Table 9.8.1-2.

Table 9.8.1-2: Maximum Step 1 & 2 PECsw and PECsed values for Sulfoxaflor metabolites

Crop	Step	Region/ season application	X11719474		X11519540	
			PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Winter cereal Spring cereal	1	---	16.72	5.01	1.75	0.25
	2	NEU, Mar – May	2.45 (1.35)	0.73 (0.40)	0.21 (0.12)	0.03 (0.02)
		SEU, Mar – May	4.61 (2.53)	1.38 (0.76)	0.42 (0.25)	0.06 (0.03)
Winter oilseed rape Spring oilseed rape	1	---	16.72	5.01	1.75	0.25
	2	NEU, Mar – May	2.02 (1.11)	0.60 (0.33)	0.08 (0.05)	0.01 (0.01)
		SEU, Mar – May	3.75 (2.06)	1.12 (0.62)	0.17 (0.10)	0.02 (0.01)
Cotton	1	---	16.72	5.01	1.75	0.25
	2	NEU, Mar – May	1.44 (0.79)	0.43 (0.24)	0.12 (0.07)	0.02 (0.01)
		SEU, Mar – May	2.59 (1.43)	0.78 (0.43)	0.25 (0.13)	0.03 (0.02)

Values in brackets are for respective single application
* For winter cereals and winter oilseed rape, the PECs values for respective single application in the Oct-Feb period in the NEU and SEU are the same as in brackets for Mar-May period in the NEU and SEU.

Modelling Comments: IIIA 9.8.1	Is is noted that applicant used a field DT_{50} of 40.5 for metabolite X115149540 instead of the lab value of 449.86 days used at EU level. However, this field value is also reported in the LoEP as alternative recommended endpoint for calculations, it is accepted here. Calculations were checked by zRMS and are validated.
Agreed PECsw (metabolites): IIIA 9.8.1	PECsw provided by applicant can be used for risk assessment.

IIIA 9.8.2 Initial PECsw value for slow moving water bodies

Refer to point IIIA 9.8.1 above.

IIIA 9.8.3 Short-term PECsw values for static water bodies 1-4 days after last application)

Refer to point IIIA 9.8.1 above.

IIIA 9.8.4 Short-term PECsw values for slow moving water bodies 1-4 days after last application)

Refer to point IIIA 9.8.1 above.

IIIA 9.8.5 Long-term PECsw values for static water bodies 7-42 days after last application)

Refer to point IIIA 9.8.1 above.

IIIA 9.8.6 Long-term PECsw values for slow moving water bodies 7-42 days after last application)

Refer to point IIIA 9.8.1 above.

IIIA 9.9 Fate and behaviour in air

Summary details of fate and behaviour in air as in the EFSA conclusion is shown in Tables 9.9-1 and 9.9-2

Table 9.9-1: Fate and behaviour in air

Vapour pressure [Pa] at 20 ºC	1.4×10^{-6}

Photochemical oxidative degradation in air	DT_{50} of 0.647 days derived by the Atkinson model (version 4.00). OH (12 h) concentration assumed = 1.5 x 10^6 [radicals/cm^3].
Volatilization	from plant surfaces (BBA guideline): not examined
	from soil surfaces (BBA guideline): not examined
Metabolites	None identified

Table 9.9-2: PEC (air)

Method of calculation	Calculations were not performed – they were considered not necessary as neither sulfoxaflor nor X11719474 are classified volatile or semi-volatile compounds.

IIIA 9.9.1 Spray droplet size spectrum – laboratory studies

This is not an EC data requirement / not required by Regulation (EC) 1107/2009.

IIIA 9.9.2 Drift – field evaluation

This is not an EC data requirement / not required by Regulation (EC) 1107/2009.

IIIA 9.10 Other/special studies

There are no additional European requirements for formulated products.

IIIA 9.10.1 Laboratory studies

This is not an EC data requirement / not required by Regulation (EC) 1107/2009.

IIIA 9.10.2 Field studies

This is not an EC data requirement / not required by Regulation (EC) 1107/2009.

APPENDIX 1: LIST OF DATA SUBMITTED IN SUPPORT OF THE EVALUATION

Data owner: DAS = Dow AgroSciences

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data relied on	Owner
IIIA 9.6.1/01	Jarvis, T. & Montesano, V.	2014a	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2372) and its metabolites in groundwater using the FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 groundwater scenarios. Exponent International Ltd. Report No.: 1402547.UK0-3366 Non-GLP, unpublished	Y	Y	Dow agroscience

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data relied on	Owner
IIIA 9.7.1/01	Jarvis, T. & Montesano, V.	2014b	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2372) and its Metabolites in Surface Water using the FOCUS Surface Water Scenarios. Exponent International Ltd. Report No.: 1402547.UK0-7910 Non-GLP, unpublished	Y	Y	Dow agroscience
IIIA 9.7.2/01	Jarvis, T. & Montesano, V.	2014b	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2372) and its Metabolites in Surface Water using the FOCUS Surface Water Scenarios. Exponent International Ltd. Report No.: 1402547.UK0-7910 Non-GLP, unpublished	Y	Y	Dow agroscience

APPENDIX 2: GAP

Appendix 2.1: Table of intended Core uses and GAP for GF-2372

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
Cotton	South (EL)	GF-2372	F	Aphids	WG	500 g/kg	Ground applied foliar spray, broadcast	BBCH 20-87 May-Sep	1-2	7	0.004-0.0016	300 - 1000	0.024	14	Two applications would be minimum 7 days interval.
Oilseed Rape	South (FR)	GF-2372	F	Aphids	WG	500 g/kg	Ground applied foliar spray, broadcast	BBCH 10 - 29 Sep-Dec BBCH 30 – 87 Apr-Jun	1-2	21	0.004-0.016	100-600	0.024	28	Two applications would be minimum 21 days interval. Only 1 application is allowed in the Sep-Dec interval followed by 1 application in the April-June period. If no autumn application, 2 spring applications are possible.
Cereal (Wheat, Barley, Oats, Rye, Spelt,	South (FR, IT)	GF-2372	F	Aphids	WG	500 g/kg	Ground applied foliar spray, broadcast	BBCH 12-29 Sep-Dec	1-2	21	0.004-0.016	100-600	0.024	21	Two applications would be minimum 21 days interval. Only 1 application is allowed in the Sep-Dec interval

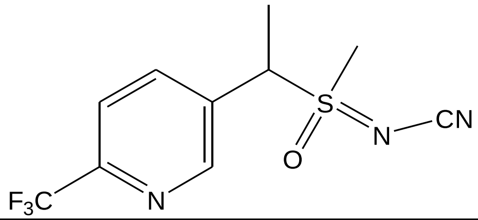
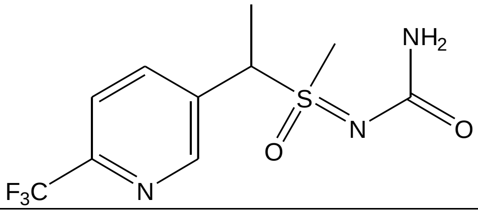
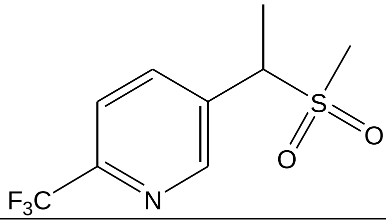
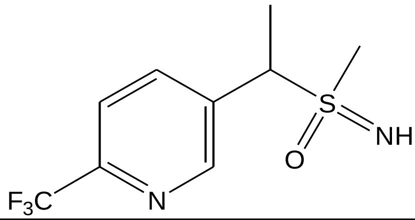
Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
Triticale) [W, S]								BBCH 30 – 87 Mar-Jul							followed by 1 application in the March-July period. If no autumn application, 2 spring applications are possible.

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

APPENDIX 3: OTHER INFORMATION

Appendix 3.1: Table of active substance and metabolites

Code Name	Chemical Name	Chemical Structure
Sulfoxaflor (parent)	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide	
X11719474 (metabolite)	1-[methyl(oxido){(1*RS*)-1-[6-(trifluoromethyl)-3-pyridinyl]ethyl}-(*RS*)λ^6-sulfanylidene]urea	
X11519540 (metabolite)	5-[(1*RS*)-1-(methylsulfonyl)ethyl]-2-(trifluoromethyl)pyridine	
X11579457 (metabolite)	5-[(1*RS*)-1-(*S*-methylsulfonimidoyl)ethyl]-2-(trifluoromethyl)pyridine	

APPENDIX 4: GUIDANCE DOCUMENTS USED IN THIS ASSESSMENT

EC (2000), Guidance Document on Persistence in Soil, Doc 9188/VI/97 rev. 8, 12.07.2000

FOCUS (1997), Soil persistence models and EU registration, Doc. 7617/VI/96, 29.2.97.

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

FOCUS (2000) "FOCUS groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202pp

FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

FOCUS (2008). "Pesticides in Air: Considerations for Exposure Assessment". Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008. 327 pp

FOCUS (2012) "Generic guidance for Tier 1 FOCUS groundwater assessments". Version 2.1, December 2012.

FOCUS (2012) Generic guidance for FOCUS surface water Scenarios, Version: 1.2, Date: December 2012

FOCUS (2014). Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Version: 1.1 Date: 18 December 2014

FOCUS (2014). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3, October 2014, 613 pp.

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

SANCO (2011) 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