Document Title

Summary of the fate and behaviour in the environment Fluopyram + Trifloxystrobin SC 500 (250+250 g/L)

Data Requirement(s)

Regulation (EC) No 1107/2009 & Regulation (EU) No 284/2013

Document MCP

Section 9: Fate and behaviour in the environment

According to the Guidance Document SANCO/10181/2013 for applicants on preparing dossiers for the approval of a chemical active substance

Date

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Bayer AG

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Version history

Date [yyyy-mm-dd]	Data points containing amendments or additions[1] and brief description	Document identifier and version number

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4, 'How to revise an Assessment Report'.

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CP 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Fluopyram was included in Annex I to Council Directive 91/414/EEC in 2013 (Regulation (EU) 802/2013 into Force on August 22nd 2013). This Supplementary Dossier contains only data which were not submitted at the time of the Annex I inclusion of Fluopyram under Council Directive 91/414/EEC and which were therefore not evaluated during the first EU review. All data which were already submitted by Bayer AG (former Bayer CropScience) for the Annex I inclusion under Council Directive 91/414/EEC are contained in the Draft Assessment Report (DAR) and its Addenda and are included in the Baseline Dossier provided by Bayer.

The formulation fluopyram + trifloxystrobin SC 500 (250+250 g/L), abbreviation FLU+TFS SC 500 (250+250), is a Suspension Concentrate (SC) formulation containing 250 g/L of fluopyram and 250 g/L trifloxystrobin. This formulation is registered throughout Europe under trade names such as Luna Sensation, Luna Sensation SC and Moon Sensation. FLU+TFS SC 500 (250+250) was not a representative formulation of Bayer AG for the Annex I inclusion of Fluopyram under Council Directive 91/414/EEC.

FLU+TFS SC 500 is an end use product proposed for use in the field on grapes and for soil-less cultivation in greenhouse based on the application pattern shown below.

Table 9.1- 1: Intended application pattern

Crop	Timing of application (range)	Number of applications	Application interval [days]	Maximum label rate (range) [L prod./ha]	Maximum application rate, individual treatment (ranges) [kg a.s./ha] Fluopyram
Grapes	BBCH 53-73	2	7	0.2	0.050
Lettuce (soil-less cultivation, high-tech greenhouse)	BBCH 12-49	2	7	0.8	0.200

CP 9.1 Fate and behaviour in soil

CP 9.1.1 Rate of degradation in soil

For information on the rate of degradation in soil please refer to Document MCA, Section 7.1.2.

CP 9.1.1.1 Laboratory studies

For information on laboratory studies please refer to Document MCA, Section 7.1.2.1.

CP 9.1.1.2 Field studies

For information on field studies please refer to Document MCA, Section 7.1.2.2.

CP 9.1.1.2.1 Soil dissipation studies

For information on field dissipation studies please refer to Document MCA, Section 7.1.2.2.1.

CP 9.1.1.2.2 Soil accumulation studies

For information on field accumulation studies please refer to Document MCA, Section 7.1.2.2.2.

CP 9.1.2 Mobility in the soil

For information on mobility studies please refer to Document MCA, Section 7.1.4.

CP 9.1.2.1 Laboratory studies

For information on laboratory studies please refer to Document MCA, Section 7.1.4.1.

CP 9.1.2.2 Lysimeter studies

For information on lysimeter studies please refer to Document MCA, Section 7.1.4.2.

CP 9.1.2.3 Field leaching studies

For information on field leaching studies please refer to Document MCA, Section 7.1.4.3.

CP 9.1.3 Estimation of concentrations in soil

Calculations of predicted environmental concentrations in soil (PEC_{soil}) are presented below.

Endpoints for PEC_{soil}

Table 9.1.3- 1: Modelling input parameters for fluopyram and its metabolites

Compound	Fluopyram	Fluopyram-7-hydroxy (FLU-7-OH)	Trifluoroacetic acid (TFA)
Molecular mass (g/mol)	396.72	412.72	114.02
Molar mass corr. factor	1	1.0403	0.2874
Max. occurrence in soil [%]	100	5.8	14.8
$DisT_{50}$ in soil (d)	1000*	85.52 [1)]	50.3 [2)]

* default
1) worst case lab, non-normalized
2) worst case $DisT_{50}$, including default degradation and leaching

PEC_{soil} modelling approach

The predicted environmental concentrations in soil (PEC_{soil}) for the active substance fluopyram and its metabolites fluopyram-7-hydroxy (FLU-7-OH) and trifluoroacetic acid (TFA) were calculated based on a first tier approach using a Microsoft® Excel spreadsheet under the assumption of an even distribution of the compound in the upper 0-5 cm soil layer. A standard soil density of 1.5 g/cm^3 was assumed. Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the recommendations of the FOCUS groundwater guidance paper (FOCUS 2014a[1]).

Predicted environmental concentrations in soil (PEC_{SOIL})

Important remark by the applicant: The modelling core information and the PEC_{soil} values as presented below are interim values and are therefore subject to change until final modelling input parameters can be established. The applicant intends to provide final modelling core information and final PEC_{soil} values latest by end of March 2022.

Data Point:	KCP 9.1.3/01
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU): Core PECgw, PECsw, PECsoil EUR - Modelling core info document for groundwater, surface water and soil risk assessment in Europe
Report No:	EnSa-21-0077
Document No:	M-763252-01-1
Guideline(s) followed in study:	None
Deviations from current test guideline:	Current guideline not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

This document summarises the substance data for fluopyram and its metabolites as used for the purpose of soil risk assessment.

Modelling reports utilising this core info document should have the substance data presented in the form as shown in **Table 9.1.3- 1**.

[1] FOCUS, 2014a: Generic Guidance for Tier 1 FOCUS Groundwater Assessments, version 2.2

Data Point:	KCP 9.1.3/02
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolites: PECsoil EUR - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0075
Document No:	M-763355-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Please note: The modelling report is considering several use scenarios. Only those relevant for FLU + TFS SC 500 are presented here.

Methods and Materials:

The predicted environmental concentrations in soil (PEC_{soil}) of fluopyram and its metabolites fluopyram-7-hydroxy (FLU-7-OH) and trifluoroacetic acid (TFA) were calculated in a first tier approach using a Microsoft® Excel spreadsheet. The use of fluopyram in grapes (modelling crop: vines) was assessed according to Good Agricultural Practice (GAP) under European cropping conditions.

A soil mixing depth of 20 cm was used for the calculation in vines.

Detailed application data used for calculation of PEC_{soil} were compiled in Table 9.1.3- 2.

Substance Specific Parameters: PEC_{soil} calculations were based on a default $DisT_{50}$ of 1000 days (worst-case non-normalized trigger value (SFO) for the parent compound fluopyram as worst case approach.

Table 9.1.3- 2: Application pattern used for PEC_{soil} calculations of fluopyram

Individual Crop	FOCUS crop used for Interception	Application				Amount reaching the soil per application
		Rate per Season	Interval	Plant Interception	BBCH Stage	
		[g a.s./ha]	[days]	[%]		[g a.s./ha]
Grapes	Vines	2 × 500	7	2 × 60	53 - 73	2 × 20.0

Findings: The PEC_{soil} values for fluopyram and its metabolites are summarized in the tables below.

Table 9.1.3- 3: PEC_{soil} for fluopyram on vines, 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval

PEC_{soil} (mg/kg)		Vines			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.027	-	0.053	-
Short term	24h	0.027	0.027	0.053	0.053
	2d	0.027	0.027	0.053	0.053
	4d	0.027	0.027	0.053	0.053
Long term	7d	0.027	0.027	0.053	0.053
	14d	0.026	0.027	0.053	0.053
	21d	0.026	0.026	0.052	0.053
	28d	0.026	0.026	0.052	0.053
	42d	0.026	0.026	0.052	0.052
	50d	0.026	0.026	0.051	0.052
	100d	0.025	0.026	0.050	0.051
Plateau concentration (5 cm) after year 10		0.093	-	0.185	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.119	-	0.238	-

Table 9.1.3- 4: PEC_{soil} for fluopyram-7-hydroxy on vines, 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval

PEC_{soil} (mg/kg)		Vines			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.002	-	0.003	-
Short term	24h	0.002	0.002	0.003	0.003
	2d	0.002	0.002	0.003	0.003
	4d	0.002	0.002	0.003	0.003
Long term	7d	0.002	0.002	0.003	0.003
	14d	0.001	0.002	0.003	0.003
	21d	0.001	0.001	0.003	0.003
	28d	0.001	0.001	0.002	0.003
	42d	0.001	0.001	0.002	0.003
	50d	0.001	0.001	0.002	0.003
	100d	0.001	0.001	0.001	0.002
Plateau concentration (5 cm) after year 1		<0.001	-	<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.002	-	0.003	-

Table 9.1.3- 5: PEC_{soil} for trifluoroacetic acid on vines, 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval

PEC_{soil} (mg/kg)		Vines			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	0.002	-
Short term	24h	0.001	0.001	0.002	0.002
	2d	0.001	0.001	0.002	0.002
	4d	0.001	0.001	0.002	0.002
Long term	7d	0.001	0.001	0.002	0.002
	14d	<0.001	0.001	0.002	0.002
	21d	<0.001	< 0.001	0.002	0.002
	28d	<0.001	< 0.001	0.001	0.002
	42d	<0.001	< 0.001	0.001	0.002
	50d	<0.001	< 0.001	0.001	0.002
	100d	<0.001	< 0.001	<0.001	0.001
Plateau concentration (5 cm) after year 1		<0.001	-	<0.001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.001	-	0.002	-

PEC_{soil} for trifloxystrobin and its metabolites

No soil assessment was required for trifloxystrobin and its metabolites for the renewal process of fluopyram.

CP 9.2 Fate and behaviour in water and sediment

CP 9.2.1 Aerobic mineralisation in surface water

For information on aerobic mineralisation in surface water studies please refer to Document MCA, Section 7.2.2.2.

CP 9.2.2 Water/sediment study

For information on water/sediment studies please refer to Document MCA, Section 7.2.2.3.

CP 9.2.3 Irradiated water/sediment study

For information on irradiated water/sediment studies please refer to Document MCA, Section 7.2.2.4.

CP 9.2.4 Estimation of concentrations in groundwater

Calculations of predicted environmental concentrations in groundwater (PEC_{gw}) are presented below.

Endpoints for PEC_{gw}

Table 9.2.4- 1: Modelling parameters for fluopyram and its metabolites FLU-7-OH and TFA

Compound	Fluopyram	Fluopyram-7-hydroxy (FLU-7-OH)	Trifluoroacetic acid (TFA)
Molecular mass (g/mol)	396.7	412.7	114
Water solubility (mg/L)	19 (20°C)	33.75 (25°C)	500000 (20°C)
Saturated vapour pressure (Pa)	1.2 E-6 (20°C)	1.55 E-9 (20°C)	1.0 E-6 (20 - 30 °C)
DT_{50} in soil (d)	298.1 (Tier 1, field $DegT_{50}$ matrix), 254.4 (Tier 2a 1, TDS DT_{50} lab equilibrium), 216.48 (Tier 2a 2, TDS DT_{50} field equilibrium)	17.5 (lab)	1000
TDS $f_{NE\ lab}$	0.525 (Tier 2a)	-	-
TDS $k_{des\ lab}$ (1/d)	0.0285 (Tier 2a)	-	-
Koc (mL/g)	232.1	100.2	0
Kom (mL/g)	134.7	58.1	0
Freundlich exponent	0.843	0.929	1

PEC_{gw} modelling approach

The predicted environmental concentrations in groundwater (PEC_{gw}) for the active substance fluopyram were calculated using the simulation models PEARL, PELMO and MACRO (scenario Châteaudun) following the recommendations of the FOCUS working group on groundwater scenarios.

The simulations are carried out over 26 years for pesticides which are applied every year. The simulation length increases to 46 and 66 years for pesticides which are applied only every second and third year, respectively. The first 6 years are intended as a so called 'warm up' period. The following years are taken into account for the assessment of the potential leaching behaviour. The 80th percentile of the average annual groundwater concentrations in the percolate at 1 m depth under a treated plantation were evaluated and were taken as the relevant PEC_{gw} values. In respect to the assessment of a potential groundwater contamination this shallow depth reflects a worst case. The effective long-term groundwater concentrations will be even lower due to dilution in the groundwater layer.

According to FOCUS, the calculations were conducted based on mean soil half-lives, referenced to standard temperature and moisture conditions. Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the recommendations of FOCUS 2014a[2].

A summary of important substance input parameters is given in Table 9.2.4- 1.

[2] FOCUS, 2014a: Generic Guidance for Tier 1 FOCUS Groundwater Assessments, version 2.2

CP 9.2.4.1 Calculation of concentrations in groundwater

Important remark by the applicant: The modelling core information and the PEC_{gw} values as presented below are interim values and are therefore subject to change until final modelling input parameters can be established. The applicant intends to provide final modelling core information and final PEC_{gw} values latest by end of March 2022.

For fluopyram, the metabolites fluopyram-7-hydroxy (FLU-7-OH) and trifluoroacetic acid (TFA) were considered for all use patterns in grapes.

Since FLU + TFS SC 500 is applied to lettuce in soil-less greenhouse uses, groundwater entry is not a relevant entry path.

Data Point:	KCP 9.2.4.1/02
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU): Core PECgw, PECsw, PECsoil EUR - Modelling core info document for groundwater, surface water and soil risk assessment in Europe
Report No:	EnSa-21-0077
Document No:	M-763252-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

This document summarises the substance data for fluopyram and its metabolites as used for the purpose of groundwater risk assessment. The following deterministic pesticide fate models were used in the calculations:

- FOCUS PEARL
- FOCUS PELMO
- FOCUS MACRO

The parameters correspond to standard EU requirements.

Modelling reports utilising this core info document should have the substance data presented in the form as shown in Table 9.2.4.1- 1 and Table 9.2.4.1- 2.

Table 9.2.4.1- 1: Compound input parameters for fluopyram and its metabolites

Parameter	Unit	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Common				
Molar mass	(g/mol)	396.7	412.7	114.0 / 228.0*
Solubility	(mg/L)	19	33.8	500000
at temp.	(°C)	20	25	20
Vapour pressure	(Pa)	1.20E-06	1.55E-09	1.00E-06
at temp.	(°C)	20	20	20
Freundlich exponent	(-)	0.8432	0.929	1
fne, TDS	(-)	n.a.[1] / 0.525[2) 3)]	0	0
kdes, TDS	(1/day)	n.a.[1] / 0.0285[2) 3)]	0	0
Plant uptake factor	(-)	0[1] / 0.3026[2),3)]	0[1] / 0.7256[2),3)]	0
Walker exponent	(-)	0.7	0.7	0.7
PEARL parameters				
Substance code	(-)	FLU[1] / FLU21[2] / FLU23[3)]	7OH[1] / 7OH21[2] / 7OH23[3)]	TFA[1] / TFA21[2] / TFA23[3)]
DT_{50}	(days)	298.1[1] / 254.4[2] / 216.48[3)]	17.5	1000
Formation fraction	(-)	-	0.6342	0.5402
Molar activ. energy	(kJ/mol)	65.4	65.4	65.4
Kom	(mL/g)	134.7	58.1	0
PELMO parameters				
Substance code	(-)	AS	A1	B1
Rate constant	(1/day)	0.00232[1] / 0.00272[2] / 0.0032[3)]	0.03954	0.00069
Q10	(-)	2.58	2.58	2.58
Koc	(mL/g)	232.1	100.2	0
MACRO parameters				
Substance code	(-)	FLU[1] / FLU21[2] / FLU23[3)]	7OH[1] / 7OH21[2] / 7OH23[3)]	TFA[1] / TFA21[2] / TFA23[3)]
Exponent moisture	(-)	0.49	0.49	0.49
Exponent temperature	(1/K)	0.0948	0.0948	0.0948
FRACEQ	(-)	n.a.[1] / 0.344[2)3)]	0	0
SORPRATE	(1/day)	n.a.[1] / 0.0098[2)3)]	0	0

1) Tier 1
2) Tier 2a 1
3) Tier 2a 2
*) Pelmo: Molar mass of TFA multiplied by 2, in combination with overall formation fraction per CF3 moiety, 0.2701., i.e. 0.5 * formation fraction per FLU molecule. This is done to adapt for limitations in PELMO with formation fractions > 1.

The model PELMO cannot deal with formation fractions > 1. Therefore, a formation fraction reflecting trifluoroacetic acid (TFA) formation per CF_3 moiety (related to max. ff 1) was used in combination with the molar mass of 2 TFA molecules. This adaptation of the formation in soil can be assumed reliable in case of TFA, since it is a non-sorbing metabolite, where equilibrium sorption is of no concern.

Table 9.2.4.1- 2: Degradation pathway related parameters for fluopyram and its metabolites

	Tier 1	Tier 2a 1	Tier 2a 2
Degradation fraction from → to (-) (FOCUS PEARL)	FLU → 7OH: 0.6342 FLU → TFA: 0.5402	FLU21 → 7OH21: 0.6342 FLU21 → TFA21: 0.5402	FLU23 → 7OH23: 0.6342 FLU23 → TFA23: 0.5402
Degradation rate from → to (1/day) (FOCUS PELMO) a), b)	Active Substance → A1: 0.0014748 Active Substance → B1: 6.28E-04 Active Substance → BR/CO2: 2.23E-04 A1 → BR/CO2: 0.0395406 B1 → BR/CO2: 6.93E-04	Active Substance → A1: 0.0017280 Active Substance → B1: 7.36E-04 Active Substance → BR/CO2: 2.61E-04 A1 → BR/CO2: 0.0395406 B1 → BR/CO2: 6.93E-04	Active Substance → A1: 0.0020306 Active Substance → B1: 8.65E-04 Active Substance → BR/CO2: 3.06E-04 A1 → BR/CO2: 0.0395406 B1 → BR/CO2: 6.93E-04
Conversion factor from → to (-) (FOCUS MACRO) c)	FLU → 7OH: 0.659777737 7OH → TFA: 0.155257118	FLU21 → 7OH21: 0.6597777 FLU21 → TFA21: 0.1552571	FLU23 → 7OH23: 0.6597777 FLU23 → TFA23: 0.1552571

a) Calculated as ln(2) / DT50 × formation fraction
b) formation fraction of TFA (B1) divided by 2 for adaptation to limitations in PELMO
c) Calculated as molar mass / molar mass predecessor × formation fraction

Data Point:	KCP 9.2.4.1/03
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 1) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0026
Document No:	M-763352-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Data Point:	KCP 9.2.4.1/04
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2a 1, appl. every year) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0053
Document No:	M-763421-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Data Point:	KCP 9.2.4.1/05
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2a 1, appl. every 2nd year) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0054
Document No:	M-763428-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Data Point:	KCP 9.2.4.1/06
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2a 1, appl. every 3rd year) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0055
Document No:	M-763423-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Data Point:	KCP 9.2.4.1/07
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2a 3, appl. every year) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0064
Document No:	M-763424-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Data Point:	KCP 9.2.4.1/08
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2a 3, appl. every 2nd year) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0065
Document No:	M-763425-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Data Point:	KCP 9.2.4.1/09
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2a 3, appl. every 3rd year) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0066
Document No:	M-763426-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Please note: The modelling reports are considering several use scenarios. Only those relevant for FLU + TFS SC 500 in grapes are presented here.

Methods and Materials:

Predicted environmental concentrations of the active substance fluopyram and its major soil degradation products in groundwater recharge (PEC_{gw}) were calculated for the use in Europe, using the simulation models FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4. PEC_{gw} were evaluated as the 80th percentile of the mean annual leachate concentration at 1 m soil depth. Model parameters and scenarios consisting of weather, soil, and crop data were used as proposed by FOCUS

(2014a,b[1,3]). The use of fluopyram in grapes (modelling crop: vines) was assessed according to Good Agricultural Practice (GAP) under European cropping conditions.

Detailed application data used for simulation of PEC_{gw} are compiled in Table 9.2.4.1- 3.

Table 9.2.4.1- 3: Application pattern used for PEC_{gw} calculations of fluopyram

Individual crop	FOCUS crop	Rate	Interval	Plant interception	BBCH stage	Amount reaching soil
		(g a.s./ha)	(days)	(%)	(-)	(g a.s./ha)
Vines I	Vines	2 × 50	7	2 × 60	53 - 73	2 × 20.000
Vines II	Vines	2 × 50	7	2 × 75	53 - 73	2 × 12.500

Input parameters – tiered approach:

A detailed description of the parameters used at the different steps is presented in Table 9.2.4.1- 4. More details on the selection of input parameter are given in the text below the table.

Table 9.2.4.1- 4: Tiered approach for fluopyram and its metabolites used for modelling

	Tier 1		Tier 2a 1		Tier 2a 2	
	DT_{50}	TSCF	DT_{50}	TSCF	DT_{50}	TSCF
FLU	298.1 a)	0 a)	254.4 b)	0.3026 f)	216.48 c)	0.3026 f)
FLU-7-OH	17.5 d)	0 e)	17.5 d)	0.7256 f)	17.5 d)	0.7256 f)
TFA	1000 e)	0 e)	1000 e)	0.17 g)	1000 e)	0.17 g)

a) $DegT_{50\ field\ matrix}$
b) TDS, DT_{50} lab equilibrium
c) TDS, DT_{50} field equilibrium
d) laboratory data
e) FOCUS worst case default
f) TSCF based on Briggs equation
g) TSCF based on experimental data

Rate of degradation of fluopyram

Tier 1: The geometric mean field $DegT_{50}$ matrix value of 298.1 d derived from field dissipation studies was used for fluopyram.

Tier 2a: Degradation and time-dependent sorption studies showed aged-sorption effects for fluopyram. A geomean laboratory DT_{50} equilibrium of 254.4 d was used as Tier 2a 1 in groundwater assessment. At Tier 2a 2 a geomean field DT_{50} equilibrium of 216.5 d was used in groundwater assessment for fluopyram. In both cases, laboratory data for f_{NE} and k_{des} were used in combination with the DT_{50} equilibrium.

[3] FOCUS, 2014b: Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU: The Final Report of the Ground Water Work Group of FOCUS EC Document Reference: Sanco/13144/2010 version 3, 613 pp.

Plant uptake (TSCF) of fluopyram and its metabolites

Tier 1: For fluopyram and its metabolites a TSCF of 0 can be used for modelling as a first tier.

Tier 2a: As a more realistic tier a TSCF based on the Briggs equation of 0.3026 (fluopyram) and 0.7256 (FLU-7-OH) should be taken into account.

For a more realistic consideration of the plant uptake of TFA, a hydroponic plant uptake study has been carried out with cereal plants. As a second tier, a TSCF of 0.17 should be taken into account.

Input parameters for fluopyram and its metabolites were used as summarised in Table 9.2.4.1- 1 and Table 9.2.4.1- 2.

Application dates for the simulation runs were defined following the crop event dates of the respective crop and scenario (see Table 9.2.4.1- 5) as given by FOCUS (2014b). Crop interception was taken into account according to the BBCH growth stage, as recommended by FOCUS (2014a).

For use patterns with large application time windows, multiple starting times for modelling were chosen to cover the full application timeframe given in the GAP. This was done according to the proposal of the tool AppDate (Klein 2019). For application windows > 60 d, the earliest and the latest possible application dates were chosen for modelling. For windows > 90 d, a further application date was set to the middle of the considered application window according to AppDate.

Table 9.2.4.1- 5: **First application dates and related information for fluopyram as used for the simulation runs; offset is relevant only for relative application dates, two sets of data are provided for crops with two seasons**

Individual crop	Vines I	Vines II
Repeat interval for app. events	Every year Every 2nd year Every 3rd year	Every year Every 2nd year Every 3rd year
Application technique	Spray	Spray
Absolute / Relative to	Absolute	Absolute
Scenario	1st app. date (Julian day) Offset	1st app. date (Julian day) Offset
Chateaudun	24 May (144) -	14 Aug (226) -
Hamburg	03 Jun (154) -	31 Jul (212) -
Jokioinen	- -	- -
Kremsmuenster	03 Jun (154) -	31 Jul (212) -
Okehampton	- -	- -
Piacenza	24 May (144) -	14 Aug (226) -
Porto	14 May (134) -	09 Aug (221) -
Sevilla	04 May (124) -	10 Jul (191) -
Thiva	01 May (121) -	17 Jul (198) -

Findings:

PEC_{gw} for use patterns in grapes were evaluated as the 80th percentile of the mean annual leachate at 1 m soil depth PEC_{gw} values for fluopyram and its metabolites are given in the following tables.

Tier 1: DT_{50} soil for fluopyram based on field data

Table 9.2.4.1- 6: Tier 1 PEC_{gw} for fluopyram and its metabolites on Vines I (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines I	Chateaudun	0.699	0.675	0.098	0.093	2.689	2.604
	Hamburg	0.606	0.679	0.092	0.101	1.990	2.683
	Kremsmuenster	0.460	0.576	0.065	0.082	1.445	1.647
	Piacenza	0.554	0.590	0.078	0.085	3.034	1.675
	Porto	0.281	0.358	0.052	0.068	1.103	1.206
	Sevilla	0.382	0.130	0.063	0.028	2.522	5.657
	Thiva	0.422	0.395	0.059	0.057	5.922	6.496
		MACRO		MACRO		MACRO	
	Châteaudun	0.258		0.040		3.194	

Table 9.2.4.1- 7: Tier 1 PEC_{gw} for fluopyram and its metabolites on Vines II (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 75% interception, 7 d app. interval

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chateaudun	0.365	0.331	0.055	0.050	1.695	1.652
	Hamburg	0.321	0.341	0.051	0.056	1.244	1.676
	Kremsmuenster	0.235	0.289	0.037	0.046	0.916	1.031
	Piacenza	0.328	0.336	0.048	0.053	1.949	1.048
	Porto	0.154	0.194	0.031	0.041	0.715	0.765
	Sevilla	0.174	0.043	0.031	0.011	1.575	3.519
	Thiva	0.204	0.149	0.031	0.026	3.702	4.065
		MACRO		MACRO		MACRO	
	Châteaudun	0.090		0.016		1.435	

Tier 2a 1: DT_{50} soil for fluopyram (TDS) based on laboratory data

Annual application

Table 9.2.4.1- 8: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Vines I (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval, annual application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines I	Chateaudun	0.290	0.224	0.050	0.042	2.681	2.476
	Hamburg	0.283	0.250	0.054	0.052	1.957	2.512
	Kremsmuenster	0.203	0.221	0.039	0.045	1.457	1.591
	Piacenza	0.257	0.296	0.044	0.057	2.993	1.622
	Porto	0.135	0.157	0.034	0.041	1.094	1.123
	Sevilla	0.131	0.016	0.030	0.006	2.434	5.142
	Thiva	0.139	0.060	0.026	0.015	5.792	5.880
		MACRO		MACRO		MACRO	
	Châteaudun	0.003		0.003		3.124	

Table 9.2.4.1- 9: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Vines II (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 75% interception, 7 d app. interval, annual application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chateaudun	0.131	0.087	0.026	0.020	1.688	1.558
	Hamburg	0.135	0.108	0.028	0.026	1.231	1.568
	Kremsmuenster	0.093	0.102	0.020	0.022	0.921	0.999
	Piacenza	0.143	0.158	0.026	0.033	1.911	1.006
	Porto	0.068	0.078	0.019	0.023	0.704	0.712
	Sevilla	0.054	0.004	0.013	0.002	1.524	3.216
	Thiva	0.060	0.015	0.012	0.005	3.634	3.666
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		1.417	

Biennial application

Table 9.2.4.1- 10: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Vines I (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval, biennial application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines I	Chateaudun	0.103	0.080	0.021	0.017	1.215	1.388
	Hamburg	0.117	0.109	0.026	0.026	0.963	1.049
	Kremsmuenster	0.073	0.083	0.016	0.019	0.721	0.849
	Piacenza	0.088	0.106	0.018	0.023	1.532	0.905
	Porto	0.045	0.055	0.014	0.018	0.522	0.547
	Sevilla	0.041	0.005	0.011	0.003	1.360	2.648
	Thiva	0.042	0.019	0.009	0.006	2.308	3.291
		MACRO		MACRO		MACRO	
	Châteaudun	0.001		0.001		1.587	

Table 9.2.4.1- 11: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Vines II (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 75% interception, 7 d app. interval, biennial application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chateaudun	0.048	0.034	0.011	0.008	0.772	0.875
	Hamburg	0.055	0.051	0.014	0.013	0.591	0.661
	Kremsmuenster	0.033	0.038	0.008	0.010	0.458	0.531
	Piacenza	0.049	0.057	0.011	0.013	0.977	0.576
	Porto	0.022	0.026	0.008	0.010	0.333	0.345
	Sevilla	0.016	0.002	0.005	0.001	0.853	1.693
	Thiva	0.016	0.006	0.004	0.002	1.457	2.020
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		0.739	

Triennial application

Table 9.2.4.1- 12: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Vines I (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval, triennial application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines I	Chateaudun	0.055	0.042	0.013	0.010	0.842	0.992
	Hamburg	0.061	0.057	0.014	0.015	0.621	0.711
	Kremsmuenster	0.042	0.046	0.010	0.011	0.495	0.590
	Piacenza	0.048	0.059	0.011	0.014	0.932	0.551
	Porto	0.023	0.028	0.008	0.010	0.335	0.355
	Sevilla	0.020	0.002	0.006	0.001	0.787	1.579
	Thiva	0.020	0.009	0.005	0.003	1.611	2.160
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		1.018	

Table 9.2.4.1- 13: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Vines II (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 75% interception, 7 d app. interval, triennial application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chateaudun	0.025	0.018	0.006	0.005	0.531	0.624
	Hamburg	0.029	0.026	0.008	0.008	0.390	0.445
	Kremsmuenster	0.019	0.020	0.005	0.006	0.306	0.358
	Piacenza	0.025	0.030	0.006	0.008	0.602	0.353
	Porto	0.011	0.013	0.004	0.005	0.213	0.224
	Sevilla	0.007	0.001	0.003	<0.001	0.497	0.973
	Thiva	0.007	0.003	0.002	0.001	0.976	1.362
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		0.512	

Tier 2a 2: DT_{50} soil for fluopyram (TDS) based on field data

Annual application

Table 9.2.4.1- 14: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Vines I (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval, annual application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines I	Chateaudun	0.147	0.107	0.035	0.028	2.724	2.521
	Hamburg	0.157	0.135	0.041	0.038	2.003	2.613
	Kremsmuenster	0.109	0.120	0.029	0.033	1.476	1.623
	Piacenza	0.142	0.176	0.033	0.046	3.012	1.652
	Porto	0.066	0.082	0.024	0.030	1.098	1.151
	Sevilla	0.057	0.004	0.019	0.003	2.473	5.216
	Thiva	0.057	0.020	0.016	0.008	5.818	5.965
		MACRO		MACRO		MACRO	
	Châteaudun	0.001		0.001		3.150	

Table 9.2.4.1- 15: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Vines II (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 75% interception, 7 d app. interval, annual application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chateaudun	0.063	0.038	0.017	0.013	1.710	1.585
	Hamburg	0.073	0.056	0.021	0.019	1.249	1.630
	Kremsmuenster	0.047	0.053	0.014	0.016	0.932	1.017
	Piacenza	0.078	0.092	0.019	0.027	1.925	1.021
	Porto	0.033	0.039	0.013	0.016	0.708	0.730
	Sevilla	0.021	0.001	0.008	0.001	1.544	3.260
	Thiva	0.023	0.004	0.007	0.003	3.644	3.718
		MACRO		MACRO		MACRO	
	Châteaudun	0.015		0.005		1.405	

Biennial application

Table 9.2.4.1- 16: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Vines I (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval, biennial application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines I	Chateaudun	0.048	0.034	0.014	0.011	1.227	1.399
	Hamburg	0.060	0.055	0.019	0.019	0.982	1.087
	Kremsmuenster	0.036	0.040	0.011	0.013	0.725	0.865
	Piacenza	0.045	0.058	0.013	0.017	1.540	0.916
	Porto	0.020	0.026	0.009	0.013	0.527	0.557
	Sevilla	0.016	0.001	0.006	0.001	1.372	2.700
	Thiva	0.015	0.005	0.005	0.003	2.317	3.344
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		1.581	

Table 9.2.4.1- 17: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Vines II (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 75% interception, 7 d app. interval, biennial application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chateaudun	0.021	0.013	0.007	0.005	0.780	0.881
	Hamburg	0.027	0.024	0.010	0.009	0.609	0.685
	Kremsmuenster	0.015	0.017	0.006	0.007	0.461	0.538
	Piacenza	0.024	0.030	0.007	0.010	0.983	0.583
	Porto	0.009	0.012	0.005	0.007	0.336	0.352
	Sevilla	0.006	0.001	0.003	<0.001	0.858	1.725
	Thiva	0.005	0.002	0.002	0.001	1.463	2.051
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		0.738	

Triennial application

Table 9.2.4.1- 18: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Vines I (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval, triennial application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines I	Chateaudun	0.024	0.017	0.008	0.006	0.849	1.003
	Hamburg	0.030	0.027	0.010	0.010	0.627	0.723
	Kremsmuenster	0.019	0.022	0.007	0.008	0.499	0.595
	Piacenza	0.024	0.031	0.007	0.011	0.931	0.534
	Porto	0.009	0.012	0.005	0.007	0.337	0.359
	Sevilla	0.007	0.001	0.003	0.001	0.790	1.571
	Thiva	0.007	0.003	0.003	0.001	1.623	2.187
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		1.020	

Table 9.2.4.1- 19: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Vines II (with FOCUS PEARL/ PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 75% interception, 7 d app. interval, triennial application

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Fluopyram		Fluopyram-7-hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chateaudun	0.010	0.007	0.004	0.003	0.534	0.630
	Hamburg	0.014	0.012	0.005	0.005	0.394	0.452
	Kremsmuenster	0.008	0.009	0.003	0.004	0.307	0.362
	Piacenza	0.012	0.015	0.004	0.006	0.602	0.356
	Porto	0.004	0.006	0.003	0.004	0.214	0.226
	Sevilla	0.002	<0.001	0.001	<0.001	0.498	0.973
	Thiva	0.002	0.001	0.001	0.001	0.977	1.382
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		0.520	

Conclusion:

Following a tiered approach for all intended uses of FLU + TFS SC 500 in grapes there are no concerns for groundwater from the active substance fluopyram and its metabolites.

In Table 9.2.4.1- 20 to Table 9.2.4.1- 40 the maximum PEC_{gw} values of fluopyram and its metabolites for FOCUS PEARL/ PELMO/ MACRO calculations for all use patterns in grapes are given at Tier 1 (Table 9.2.4.1- 20 to Table 9.2.4.1- 22), Tier 2a 1 (Table 9.2.4.1- 23 to Table 9.2.4.1- 31), and Tier 2a 2 (Table 9.2.4.1- 32 to Table 9.2.4.1- 40).

Tier 1: DT_{50} soil for fluopyram based on field data

Table 9.2.4.1- 20: Maximum FOCUS PEARL PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 1

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.699	0.098	5.922
Vines II, 2×50 g a.s./ha	0.365	0.055	3.702

Table 9.2.4.1- 21: Maximum FOCUS PELMO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 1

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.679	0.101	6.496
Vines II, 2×50 g a.s./ha	0.341	0.056	4.065

Table 9.2.4.1- 22: Maximum FOCUS MACRO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 1

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.258	0.040	3.194
Vines II, 2×50 g a.s./ha	0.090	0.016	1.435

Tier 2a 1: DT_{50} soil for fluopyram (TDS) based on laboratory data

Annual application

Table 9.2.4.1- 23: Maximum FOCUS PEARL PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, annual application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.290	0.054	5.792
Vines II, 2×50 g a.s./ha	0.143	0.028	3.634

Table 9.2.4.1- 24: Maximum FOCUS PELMO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, annual application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.296	0.057	5.880
Vines II, 2×50 g a.s./ha	0.158	0.033	3.666

Table 9.2.4.1- 25: Maximum FOCUS MACRO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, annual application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.003	0.003	3.124
Vines II, 2×50 g a.s./ha	<0.001	<0.001	1.417

Biennial application

Table 9.2.4.1- 26: Maximum FOCUS PEARL PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, biennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.117	0.026	2.308
Vines II, 2×50 g a.s./ha	0.055	0.014	1.457

Table 9.2.4.1- 27: Maximum FOCUS PELMO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, biennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.109	0.026	3.291
Vines II, 2×50 g a.s./ha	0.057	0.013	2.020

Table 9.2.4.1- 28: Maximum FOCUS MACRO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, biennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.001	0.001	1.587
Vines II, 2×50 g a.s./ha	<0.001	<0.001	0.739

Triennial application

Table 9.2.4.1- 29: Maximum FOCUS PEARL PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, triennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.061	0.014	1.611
Vines II, 2×50 g a.s./ha	0.029	0.008	0.976

Table 9.2.4.1- 30: Maximum FOCUS PELMO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, triennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.039	0.015	2.160
Vines II, 2×50 g a.s./ha	0.030	0.008	1.362

Table 9.2.4.1- 31: Maximum FOCUS MACRO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 1, triennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	<0.001	<0.001	1.018
Vines II, 2×50 g a.s./ha	<0.001	<0.001	0.512

Tier 2a 2: DT_{50} soil for fluopyram (TDS) based on field data

Annual application

Table 9.2.4.1- 32: Maximum FOCUS PEARL PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, annual application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.157	0.041	5.818
Vines II, 2×50 g a.s./ha	0.078	0.021	3.644

Table 9.2.4.1- 33: Maximum FOCUS PELMO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, annual application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.176	0.046	5.965
Vines II, 2×50 g a.s./ha	0.092	0.027	3.718

Table 9.2.4.1- 34: Maximum FOCUS MACRO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, annual application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	<0.001	0.001	3.150
Vines II, 2×50 g a.s./ha	0.015	0.005	1.405

Biennial application

Table 9.2.4.1- 35: Maximum FOCUS PEARL PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, biennial application

Vines I, 2×50 g a.s./ha	0.060	0.019	2.317
Vines II, 2×50 g a.s./ha	0.027	0.010	1.463

Table 9.2.4.1- 36: Maximum FOCUS PELMO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, biennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.058	0.019	3.344
Vines II, 2×50 g a.s./ha	0.030	0.010	2.051

Table 9.2.4.1- 37: Maximum FOCUS MACRO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, biennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	<0.001	<0.001	1.581
Vines II, 2×50 g a.s./ha	<0.001	<0.001	0.738

Triennial application

Table 9.2.4.1- 38: Maximum FOCUS PEARL PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, triennial application

Vines I, 2×50 g a.s./ha	0.030	0.010	1.623
Vines II, 2×50 g a.s./ha	0.014	0.005	0.977

Table 9.2.4.1- 39: Maximum FOCUS PELMO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, triennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	0.031	0.011	2.187
Vines II, 2×50 g a.s./ha	0.015	0.006	1.382

Table 9.2.4.1- 40: Maximum FOCUS MACRO PEC_{gw} results of fluopyram and its metabolites in µg/L for the uses assessed – Tier 2a 2, triennial application

Use pattern	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	<0.001	<0.001	1.020
Vines II, 2×50 g a.s./ha	<0.001	<0.001	0.520

Predicted environmental concentrations in groundwater (PEC_{gw}) for fluopyram in lettuce (soil-less greenhouse use)

The exposure assessment model GEM 3.3.2 (Greenhouse Emission Model 3.3.2) contains greenhouse scenarios, for both soil-less and soil-bound cultivation. Predicted environmental concentrations in ground water (PEC_{gw}) were only considered for soil-bound cultivation.

Since FLU + TFS SC 500 is applied to lettuce in soil-less greenhouse uses, groundwater entry is not a relevant entry path.

PEC_{gw} for trifloxystrobin and its metabolites

No groundwater assessment was required for trifloxystrobin and its metabolites for the fluopyram active substance renewal process.

CP 9.2.4.2 Additional field tests

For information on additional field studies please refer to Document MCA, Section 7.1.2.2.1.

CP 9.2.5 Estimation of concentrations in surface water and sediment

Calculations of predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) are presented below.

Endpoints for PEC_{sw}

Table 9.2.5- 1: Modelling input parameters for fluopyram and its metabolites FLU-7-OH and TFA (FOCUS sw)

Compound	Fluopyram	Fluopyram-7-hydroxy (FLU-7-OH)	Trifluoroacetic acid (TFA)
Molecular mass (g/mol)	396.72	412.72	114.02
Water solubility (mg/L)	19 (20°C)	32.75 (25°C)	500000 (20°C)
Saturated vapour pressure (Pa)	1.2 E-6 (20°C)	1.55 E-9 (20°C)	1.0 E-6 (20°C)
Koc (mL/g)	232.1	100.2	0*
Kom (mL/g)	134.7	58.1	0*
1/n	0.8432	0.9292	1*
Plant uptake factor TSCF	0	0	0
Wash off factor from crop (1/m)	50	50	50
DT_{50} in soil (d)	298.8 (field)	17.53 (lab)	1000*
DT_{50} in water (d)	909 (Step 1,2) 1000* (Step 3,4)	1000*	1000*
DT_{50} in sediment (d)	909 (Step 1,2) 1000* (Step 3,4)	1000*	1000*
DT_{50} in total system (d)	909	1000	1000
DT_{50} on canopy (d)	10*	10*	10*
Maximum occurrence (%) Water/sediment: Soil:	 100 100	 0 5.8	 0 14.8
Formation fraction in soil		0.6342, from parent	0.5402, overall from parent, total molar yield
Formation fraction in water, sediment	-	0	0

* default

PEC_{sw} modelling approach

Calculation of PEC values for the active substance according to FOCUS

$FOCUS_{sw}$ is a 4 step tiered approach:

Step 1: In this, the most conservative step, all inputs are considered as a single loading to the water body and a worst-case PEC_{sw} and PEC_{sed} is calculated.

Step 2: Individual loadings into the water body from different entry routes are considered. Scenarios are also considered for Northern and Southern Europe separately, but no specific crop scenarios are defined.

Step 3: An exposure assessment using realistic worst-case scenarios is made. The scenarios are representative for agricultural conditions in Europe and consider weather, soil, crop and different water-bodies. Simulations use the models PRZM, MACRO and TOXSWA.

Step 4: PEC values are refined by considering mitigation measures or specific scenario descriptions on a case-by-case basis.

A summary of important substance input parameters is given in Table 9.2.5- 1.

Calculation of PEC values for fluopyram according to Greenhouse Emission model (GEM 3.3.2) for use in lettuce

The exposure assessment model GEM 3.3.2 (Greenhouse Emission Model 3.3.2) is used in the pesticide registration process in the Netherlands and Europe, to assess the pesticidal exposure in high-tech greenhouses. It contains greenhouse scenarios, for both soil-less and soil-bound cultivation (Wipfler, Cornelese, et al., 2015). The model enables the calculation of predicted environmental concentration (PEC) for the protection goals 'aquatic ecosystem' and 'groundwater as source for drinking water'. Three distinct types of assessments can be carried out:

- Surface water exposure assessment for pesticides used in soil-less cultivation
- Surface water exposure assessment for pesticides used in soil-bound cultivation
- Leaching assessment to groundwater for pesticides used in soil-bound cultivation

A predecessor of this model or its corresponding scenarios are also mentioned in the EFSA protected crop guidance to be used for high-tech greenhouse assessments in Europe (EFSA, 2014, Appendix B, C).

Only soil-less cultivation was considered for the use of FLU + TFS SC 500 in lettuce.

A summary of important substance input parameters is given in Table 9.2.5- 23.

Data Point:	KCP 9.2.5.01
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU): Core PECgw, PECsw, PECsoil EUR - Modelling core info document for groundwater, surface water and soil risk assessment in Europe
Report No:	EnSa-21-0077
Document No:	M-763252-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

This document summarises the substance data for fluopyram and its metabolites as used for the purpose of surface water risk assessment.

Modelling reports utilising this core info document should have the substance data presented in the form as shown in Table 9.2.5- 2 and Table 9.2.5- 3.

Table 9.2.5- 2: Substance parameters used for fluopyram and its metabolites fluopyram-7-hydroxy (FLU-7-OH) and trifluoroacetic acid (TFA) at FOCUSsw Steps 1-2 level

Parameter	Unit	Fluopyram	Fluopyram-7-hydroxy	Trifluoroacetic acid
Molar mass	(g/mol)	396.72	412.72	114.02
Water solubility	(mg/L)	19	33.75	500000
Koc	(mL/g)	232.1	100.2	1E-10
Degradation				
Soil	(days)	298.08	1753	1000
Total system	(days)	909	1000	1000
Water	(days)	909	1000	1000
Sediment	(days)	909	1000	1000
Max occurrence				
Water / sediment	(%)	100	0	0
Soil	(%)	100	5.8	14.8

Table 9.2.5- 3: Substance parameters used for fluopyram and its metabolites at FOCUSsw Step 3-4

Parameter	Unit	Parent	Metabolite	Metabolite
Substance SWASH code		Fluopyram_Tier 1 FLU	FLU-7-hydroxy_Tier1 7OH	TFA_Tier1 TFA
General				
Molar mass	(g/mol)	396.72	412.72	114.02
Water solubility (temp.)	(mg/L)	19.0 (20 °C)	33.75 (25 °C)	500000 (20 °C)
Vapour pressure (temp.)	(Pa)	1.2E-06 (20 °C)	1.55E-09 (20 °C)	1E-06 (20 °C)
Crop processes				
Coefficient for uptake by plant (TSCF)	(-)	0	0	0
Wash-off factor	(1/m)	50	50	50
Sorption				
K_{OC}	(mL/g)	232.1	1002	0
K_{OM}	(mL/g)	134.7	58.1	0
Freundlich exponent ($^1/_n$)	(-)	0.8432	0.9292	1
Transformation				
D_{T50} in soil	(days)	298.08	17.53	1000
temperature	(°C)	20	20	20
moisture content (pF)	(log(cm))	2	2	2
formation fraction in soil	(-)	-	0.6342	0.5402
DT_{50} in water	(days)	1000	1000	1000
temperature	(°C)	20	20	20
formation fraction in water	(-)	-	-	-
DT_{50} in sediment	(days)	1000	1000	1000
temperature	(°C)	20	20	20
formation fraction in sediment	(-)	-	-	-
DT_{50} on canopy	(days)	10	10	10
Exponent for the effect of moisture				
PRZM and TOXSWA (Walker exp.)	(-)	0.7	0.7	0.7
MACRO (calibrated value)	(-)	0.49	0.49	0.49
Effect of temperature				
TOXSWA (molar activat. energy)	(kJ/mol)	65.4	65.4	65.4
MACRO (effect of temperature)	(1/K)	0.0948	0.0948	0.0948
PRZM (Q_{10})	(-)	2.58	2.58	2.58

Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) of fluopyram and its metabolites

For fluopyram, the metabolites fluopyram-7-hydroxy (FLU-7-OH) and trifluoroacetic acid (TFA) were considered.

Important remark by the applicant: The modelling core information and the PEC_{sw} and PEC_{sed} values as presented below are interim values and are therefore subject to change until final modelling input parameters can be established. The applicant intends to provide final modelling core information and final PEC_{sw} and PEC_{sed} values latest by end of March 2022.

The overall surface water assessment involving fluopyram and its metabolites consists of the following calculations:

Data Point:	KCP 9.2.5/02
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite: PECsw,sed FOCUS EUR (tier 1) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0067
Document No:	M-763460-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Data Point:	KCP 9.2.5/03
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite: PECsw,sed FOCUS EUR (tier 1) - Use in apples, spring cereals, winter cereals and vines in Europe
Report No:	EnSa-21-0069
Document No:	M-763417-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Please note: The modelling reports are considering several use scenarios. Only those relevant for FLU + TFS SC 500 are presented here.

Methods and Materials:

Predicted environmental concentrations of the active substance fluopyram and its metabolites in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for the use in Europe, employing the tiered FOCUS Surface Water (SW) approach (FOCUS 2001, 2015). All relevant entry routes of a compound into surface water (principally a combination of spray drift and runoff/erosion or drain flow) were considered in these calculations.

The use of fluopyram in grapes (FOCUS crop: vines, late) was assessed according to Good Agricultural Practice (GAP) in Europe. Detailed application parameters are presented in Table 9.2.5- 4.

Table 9.2.5- 4: Application pattern used for PEC_{sw} calculations of fluopyram

Crop	BBCH stage	Rate [g a.s./ha]	Interval [days]	FOCUS crop (crop group)	Season	Crop cover
Vines	53 - 73	2 × 50	7	Vines, late applications (vines / late)	Spring (Mar. - May) Summer (Jun. - Sep.)	Full canopy

Substance input parameter are summarised in Table 9.2.5- 2 and Table 9.2.5- 3.

For the use in grapes in addition to FOCUS Step 1-2 values, FOCUS Step 3 values were calculated for the active substance fluopyram and its metabolites fluopyram-7-hydroxy (FLU-7-OH) and trifluoroacetic acid (TFA). In FOCUS Step 3, the application date for each scenario is determined by the Pesticide Application Timer (PAT), which is part of the FOCUS SW Scenarios. The user may only define an application time window. The actual application date is then set by the PAT in such a way that there are at least 10 mm of rainfall in the first 10 days after application, and at the same time less than 2 mm of rain per day in a five day period around the date of application. If no such date can be found within the application time window, the above rules are step-wise relaxed. Information on application dates can be found in Table 9.2.5- 5.

Table 9.2.5- 5: Application dates of fluopyram for the FOCUS Step 3 calculations

Parameter	Vines, early		Vines, late	
PAT start date rel./absolute	Absolute		Absolute	
Appl. method (appl. type)	Air blast (2 – appl. foliar linear, 4 cm)		Air blast (2 – appl. foliar linear, 4 cm)	
No of appl.	2		2	
PAT window range	37		37	
Appl. interval	7d		7d	
Scenarios	PAT start/end date (Julian day)	Application date	PAT start/end date (Julian day)	Application date
D6 Ditch	12-Mar/18-Apr (71/108)	14-Mar 09-Apr	30-May/06-Jul (150/187)	30-May 06-Jun
R1 Pond/Stream	19-May/25-Jun (139/176)	31-May 12-Jun	19-Jul/25-Aug (200/237)	28-Jul 20-Aug
R2 Stream	14-May/20-Jun (134/171)	20-May 27-May	09-Aug/15-Sep (221/258)	09-Aug 14-Sep
R3 Stream	24-May/30-Jun (144/181)	01-Jun 16-Jun	14-Aug/20-Sep (226/263)	14-Aug 28-Aug
R4 Stream	07-May/13-Jun (127/164)	07-May 27-May	29-Jul/04-Sep (210/247)	31-Jul 13-Aug

Findings:

FOCUS Step 1 and 2

The maximum PEC_{sw} and PEC_{sed} values for FOCUS Step 1 and 2 are given in the tables below for fluopyram and its metabolites fluopyram-7-hydroxy (FLU-7-OH) and trifluoroacetic acid (TFA) considering application in grapes (FOCUS crop: vines).

Fluopyram

Table 9.2.5- 6: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for fluopyram following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- spring -- 2×50 g a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	28.1	RunOff	27.3	63.8
Step 2					
Northern Europe	Mar. - May (Spring)	3.96	Drift	3.78	8.82
Southern Europe	Mar. - May (Spring)	5.96	RunOff	5.76	13.5

* Single applications are marked.
** TWA interval as required by ecotox

Table 9.2.5- 7: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for fluopyram following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- summer -- 2×50 g a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	28.1	RunOff	27.3	63.8
Step 2					
Northern Europe	Jun. - Sep. (Summer)	3.96	Drift	3.78	8.82
Southern Europe	Jun. - Sep. (Summer)	4.96	RunOff	4.77	11.1

* Single applications are marked.
** TWA interval as required by ecotox

Fluopyram-7-hydroxy (FLU-7-OH)

Table 9.2.5- 8: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for fluopyram-7-hydroxy following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- spring -- 2×50 g a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	1.77		1.76	1.78
Step 2					
Northern Europe	Mar. - May (Spring)	0.141	-	0.140	0.142
Southern Europe	Mar. - May (Spring)	0.282	-	0.280	0.283

* Single applications are marked.
** TWA interval as required by ecotox

Table 9.2.5- 9: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for fluopyram-7-hydroxy following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- summer -- 2×50 g a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	1.77		1.76	1.78
Step 2					
Northern Europe	Jun. - Sep. (Summer)	0.141	-	0.140	0.142
Southern Europe	Jun. - Sep. (Summer)	0.212	-	0.210	0.212

* Single applications are marked.
** TWA interval as required by ecotox

Trifluoroacetic acid (TFA)

Table 9.2.5- 10: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for trifluoroacetic acid following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- spring -- 2×50 g a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	1.42	-	1.41	<0.001
Step 2					
Northern Europe	Mar. - May (Spring)	0.113	-	0.112	<0.001 *
Southern Europe	Mar. - May (Spring)	0.226	-	0.224	<0.001 *

* Single applications are marked.
** TWA interval as required by ecotox

Table 9.2.5- 11: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for trifluoroacetic acid following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- summer -- 2×50 g a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	1.42	-	1.41	<0.001
Step 2					
Northern Europe	Jun. - Sep. (Summer)	0.113	-	0.112	<0.001 *
Southern Europe	Jun. - Sep. (Summer)	0.169	-	0.168	<0.001 *

* Single applications are marked.
** TWA interval as required by ecotox

FOCUS Step 3

The maximum PEC_{sw} and PEC_{sed} values for FOCUS Step 3 are given in the tables below for fluopyram and its metabolites fluopyram-7-hydroxy (FLU-7-OH) and trifluoroacetic acid (TFA) considering application in grapes (FOCUS crop: vines, late). The reported PEC_{sw} and PEC_{sed} values represent loadings via all relevant entry routes.

Fluopyram

Table 9.2.5- 12: FOCUS Step 3 PEC_{sw} and PEC_{sed} for fluopyram following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- early -- 2×0.05 kg a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D6	Ditch	0.860 *	Spray drift	0.124	0.754
R1	Pond	0.057	RunOff	0.051	0.286
R1	Stream	1.08	Spray drift	0.046	0.501
R2	Stream	0.840 *	Spray drift	0.033	0.384
R3	Stream	0.887 *	Spray drift	0.028	0.203
R4	Stream	0.617	Spray drift	0.038	0.288 *

* Single applications are marked.
** TWA interval as required by ecotox

Table 9.2.5- 13: FOCUS Step 3 PEC_{sw} and PEC_{sed} for fluopyram following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- late -- 2×0.05 kg a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D6	Ditch	1.14	Spray drift	0.536	1.67
R1	Pond	0.046	Spray drift	0.041	0.233
R1	Stream	0.612 *	Spray drift	0.006	0.084
R2	Stream	0.843	Spray drift	0.013	0.157
R3	Stream	0.946	Spray drift	0.101	0.591
R4	Stream	1.10	Spray drift	0.056	0.569

* Single applications are marked.
** TWA interval as required by ecotox

Fluopyram-7-hydroxy (FLU-7-OH)

Table 9.2.5- 14: FOCUS Step 3 PEC_{sw} and PEC_{sed} for FLU-7-OH following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- early -- 2×0.05 kg a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D6	Ditch	0.033	-	0.011	0.036
R1	Pond	<0.001	-	<0.001	<0.001
R1	Stream	0.016	-	<0.001	0.004
R2	Stream	0.011	-	<0.001	0.004
R3	Stream	0.008	-	<0.001	0.002
R4	Stream	0.013	-	<0.001	0.005

* Single applications are marked.
** TWA interval as required by ecotox

Table 9.2.5- 15: FOCUS Step 3 PEC_{sw} and PEC_{sed} for FLU-7- OH following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- late -- 2×0.05 kg a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*	
Step 3						
D6	Ditch	0.017	-	0.006	0.020	
R1	Pond	<0.001	*	<0.001	<0.001	*
R1	Stream	<0.001	*	<0.001	<0.001	*
R2	Stream	0.014	-	<0.001	0.004	
R3	Stream	0.010	-	<0.001	0.003	
R4	Stream	0.017	-	<0.001	0.005	

* Single applications are marked.
** TWA interval as required by ecotox

Trifluoroacetic acid (TFA)

Table 9.2.5- 16: FOCUS Step 3 PEC_{sw} and PEC_{sed} for TFA following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- early -- 2×0.05 kg a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D6	Ditch	1.03	-	0.955	0.508
R1	Pond	<0.001 *	-	<0.001	<0.001 *
R1	Stream	0.006	-	<0.001	<0.001
R2	Stream	0.004	-	<0.001	<0.001
R3	Stream	<0.001	-	<0.001	<0.001
R4	Stream	0.005	-	<0.001	<0.001

* Single applications are marked.
** TWA interval as required by ecotox

Table 9.2.5- 17: FOCUS Step 3 PEC_{sw} and PEC_{sed} for TFA following single/multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- late -- 2×0.05 kg a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D6	Ditch	0.413	-	0.380	0.204
R1	Pond	<0.001 *	-	<0.001	<0.001 *
R1	Stream	<0.001 *	-	<0.001	<0.001 *
R2	Stream	<0.001	-	<0.001	<0.001 *
R3	Stream	0.004	-	<0.001	<0.001
R4	Stream	0.007	-	<0.001	<0.001

* Single applications are marked.
** TWA interval as required by ecotox

FOCUS Step 4

The maximum PEC_{sw} values for FOCUS Step 4 are given in the tables below for fluopyram and its metabolite fluopyram-7-hydroxy (FLU-7-OH) considering application in grapes (FOCUS crop: vines, late). The reported PEC_{sw} values represent loadings via all relevant entry routes.

Fluopyram

Table 9.2.5- 18: PEC_{sw} values for fluopyram, following single/multiple applications(s) of FLU + TFS SC 500 to grapes according to surface water Step 4 (modelling use vines – early – 2×0.05 kg a.s./ha, 7d int.)

PEC_{sw} (µg/L)	Scenario	Step 4 fluopyram							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D6 Ditch	0.860	0.522	*0.464*	*0.464*	*0.464*	*0.464*		
50 %		*0.464*	*0.464*	*0.464*	*0.464*	*0.464*	*0.464*		
75 %		*0.464*	*0.464*	*0.464*	*0.464*	*0.464*	*0.464*		
90 %		*0.464*	*0.464*	*0.464*	*0.464*	*0.464*	*0.464*		
None	R1 Pond	*0.057*	*0.064*	*0.041*	*0.027*	*0.033*	*0.016*		
50 %		*0.035*	*0.039*	*0.027*	*0.020*	*0.019*	*0.009*		
75 %		*0.024*	*0.026*	*0.020*	*0.017*	*0.012*	*0.006*		
90 %		*0.018*	*0.019*	*0.016*	*0.015*	*0.008*	*0.004*		
None	R1 Stream	*1.08*	*1.08*	*1.08*	*1.08*	*0.474*	*0.245*		
50 %		*1.08*	*1.08*	*1.08*	*1.08*	*0.474*	*0.245*		
75 %		*1.08*	*1.08*	*1.08*	*1.08*	*0.474*	*0.245*		
90 %		*1.08*	*1.08*	*1.08*	*1.08*	*0.474*	*0.245*		
None	R2 Stream	0.840	0.612	*0.514*	*0.514*	*0.232*	*0.121*		
50 %		*0.514*	*0.514*	*0.514*	*0.514*	*0.232*	*0.121*		
75 %		*0.514*	*0.514*	*0.514*	*0.514*	*0.232*	*0.121*		
90 %		*0.514*	*0.514*	*0.514*	*0.514*	*0.232*	*0.121*		
None	R3 Stream	0.887	0.646	0.234	*0.165*	0.234	0.082		
50 %		0.443	0.323	*0.165*	*0.165*	0.117	0.041		
75 %		0.222	*0.165*	*0.165*	*0.165*	*0.072*	*0.037*		
90 %		*0.165*	*0.165*	*0.165*	*0.165*	*0.072*	*0.037*		
None	R4 Stream	0.617	0.527	0.527	0.527	0.230	0.119		
50 %		0.527	0.527	0.527	0.527	0.230	0.119		
75 %		0.527	0.527	0.527	0.527	0.230	0.119		
90 %		0.527	0.527	0.527	0.527	0.230	0.119		

* Maximum values coming from multiple applications are marked in italics

Table 9.2.5- 19: PEC$_{sw}$ values for fluopyram, following single/multiple applications(s) of FLU + TFS SC 500 to grapes according to surface water Step 4 (modelling use vines -- late -- 2×0.05 kg a.s./ha, 7d int.)

PEC$_{sw}$ (µg/L)	Scenario	Step 4 fluopyram							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D6 Ditch	*1.14*	*0.684*	*0.306*	*0.306*	*0.306*	*0.306*		
50 %		*0.568*	*0.341*	*0.306*	*0.306*	*0.306*	*0.306*		
75 %		*0.306*	*0.306*	*0.306*	*0.306*	*0.306*	*0.306*		
90 %		*0.306*	*0.306*	*0.306*	*0.306*	*0.306*	*0.306*		
None	R1 Pond	*0.046*	*0.054*	*0.029*	*0.015*	*0.029*	*0.015*		
50 %		*0.023*	*0.027*	*0.015*	*0.007*	*0.015*	*0.007*		
75 %		*0.012*	*0.013*	*0.007*	*0.004*	*0.007*	*0.004*		
90 %		*0.005*	*0.005*	*0.003*	*0.001*	*0.003*	*0.001*		
None	R1 Stream	0.612	0.446	0.162	0.057	0.162	0.057		
50 %		0.306	0.223	0.081	0.028	0.081	0.028		
75 %		0.153	0.112	0.040	*0.016*	0.040	*0.014*		
90 %		0.061	0.045	0.016	*0.016*	0.016	0.006		
None	R2 Stream	0.843	0.615	*0.234*	*0.234*	0.223	0.078		
50 %		0.422	0.307	*0.234*	*0.234*	0.111	*0.055*		
75 %		*0.234*	*0.234*	*0.234*	*0.234*	*0.106*	*0.055*		
90 %		*0.234*	*0.234*	*0.234*	*0.234*	*0.106*	*0.055*		
None	R3 Stream	*0.946*	*0.946*	*0.946*	*0.946*	*0.428*	*0.224*		
50 %		*0.946*	*0.946*	*0.946*	*0.946*	*0.428*	*0.224*		
75 %		*0.946*	*0.946*	*0.946*	*0.946*	*0.428*	*0.224*		
90 %		*0.946*	*0.946*	*0.946*	*0.946*	*0.428*	*0.224*		
None	R4 Stream	*1.10*	*1.10*	*1.10*	*1.10*	*0.494*	*0.257*		
50 %		*1.10*	*1.10*	*1.10*	*1.10*	*0.494*	*0.257*		
75 %		*1.10*	*1.10*	*1.10*	*1.10*	*0.494*	*0.257*		
90 %		*1.10*	*1.10*	*1.10*	*1.10*	*0.494*	*0.257*		

* Maximum values coming from multiple applications are marked in italics

Fluopyram-7-hydroxy (FLU-7-OH)

Table 9.2.5- 20: PEC_{sw} values for FLU-7-OH, following single/multiple applications(s) of FLU + TFS SC 500 to grapes according to surface water Step 4 (modelling use vines -- early 2×0.05 kg a.s./ha, 7d int.)

PEC_{sw} (µg/L)	Scenario	Step 4 FLU-7-OH							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D6 Ditch	*0.033*	*0.033*	*0.033*	*0.033*	*0.033*	*0.033*		
50 %		*0.033*	*0.033*	*0.033*	*0.033*	*0.033*	*0.033*		
75 %		*0.033*	*0.033*	*0.033*	*0.033*	*0.033*	*0.033*		
90 %		*0.033*	*0.033*	*0.033*	*0.033*	*0.033*	*0.033*		
None	R1 Pond	*<0.001*	*<0.001*	*<0.001*	*<0.001*	<0.001	<0.001		
50 %		*<0.001*	*<0.001*	*<0.001*	*<0.001*	<0.001	<0.001		
75 %		*<0.001*	*<0.001*	*<0.001*	*<0.001*	<0.001	<0.001		
90 %		*<0.001*	*<0.001*	*<0.001*	*<0.001*	<0.001	<0.001		
None	R1 Stream	*0.016*	*0.016*	*0.016*	*0.016*	*0.007*	*0.004*		
50 %		*0.016*	*0.016*	*0.016*	*0.016*	*0.007*	*0.004*		
75 %		*0.016*	*0.016*	*0.016*	*0.016*	*0.007*	*0.004*		
90 %		*0.016*	*0.016*	*0.016*	*0.016*	*0.007*	*0.004*		
None	R2 Stream	*0.011*	*0.011*	*0.011*	*0.011*	*0.005*	*0.003*		
50 %		*0.011*	*0.011*	*0.011*	*0.011*	*0.005*	*0.003*		
75 %		*0.011*	*0.011*	*0.011*	*0.011*	*0.005*	*0.003*		
90 %		*0.011*	*0.011*	*0.011*	*0.011*	*0.005*	*0.003*		
None	R3 Stream	*0.008*	*0.008*	*0.008*	*0.008*	*0.003*	*0.002*		
50 %		*0.008*	*0.008*	*0.008*	*0.008*	*0.003*	*0.002*		
75 %		*0.008*	*0.008*	*0.008*	*0.008*	*0.003*	*0.002*		
90 %		*0.008*	*0.008*	*0.008*	*0.008*	*0.003*	*0.002*		
None	R4 Stream	*0.013*	*0.013*	*0.013*	*0.013*	*0.006*	*0.003*		
50 %		*0.013*	*0.013*	*0.013*	*0.013*	*0.006*	*0.003*		
75 %		*0.013*	*0.013*	*0.013*	*0.013*	*0.006*	*0.003*		
90 %		*0.013*	*0.013*	*0.013*	*0.013*	*0.006*	*0.003*		

* Maximum values coming from multiple applications are marked in italics

Table 9.2.5- 21: **PEC_{sw} values for FLU-7-OH, following single/multiple applications(s) of FLU + TFS SC 500 to grapes according to surface water Step 4 (modelling use vines -- late -- 2×0.05 kg a.s./ha, 7d int.)**

PEC_{sw} (µg/L)	Scenario	Step 4 FLU-7-OH							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D6 Ditch	*0.017*	*0.017*	*0.017*	*0.017*	*0.017*	*0.017*		
50 %		*0.017*	*0.017*	*0.017*	*0.017*	*0.017*	*0.017*		
75 %		*0.017*	*0.017*	*0.017*	*0.017*	*0.017*	*0.017*		
90 %		*0.017*	*0.017*	*0.017*	*0.017*	*0.017*	*0.017*		
None	R1 Pond	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
50 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
75 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
90 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
None	R1 Stream	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
50 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
75 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
90 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
None	R2 Stream	*0.011*	*0.011*	*0.011*	*0.011*	*0.005*	*0.003*		
50 %		*0.011*	*0.011*	*0.011*	*0.011*	*0.005*	*0.003*		
75 %		*0.011*	*0.011*	*0.011*	*0.011*	*0.005*	*0.003*		
90 %		*0.011*	*0.011*	*0.011*	*0.011*	*0.005*	*0.003*		
None	R3 Stream	*0.010*	*0.010*	*0.010*	*0.010*	*0.005*	*0.002*		
50 %		*0.010*	*0.010*	*0.010*	*0.010*	*0.005*	*0.002*		
75 %		*0.010*	*0.010*	*0.010*	*0.010*	*0.005*	*0.002*		
90 %		*0.010*	*0.010*	*0.010*	*0.010*	*0.005*	*0.002*		
None	R4 Stream	*0.017*	*0.017*	*0.017*	*0.017*	*0.008*	*0.004*		
50 %		*0.017*	*0.017*	*0.017*	*0.017*	*0.008*	*0.004*		
75 %		*0.017*	*0.017*	*0.017*	*0.017*	*0.008*	*0.004*		
90 %		*0.017*	*0.017*	*0.017*	*0.017*	*0.008*	*0.004*		

* Maximum values coming from multiple applications are marked in italics

Calculation of PEC values for fluopyram according to Greenhouse Emission Model (GEM 3.3.2) for use in lettuce

Data Point:	KCP 9.2.5/04
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite: PECsw after application in greenhouses using greenhouse emission model (GEM 3.3.2) - Use in lettuce in the Netherlands and Europe
Report No:	EnSa-21-0068
Document No:	M-763353-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Methods and Materials:
Predicted environmental concentrations in surface water (PEC_{sw}) were estimated after use in high-tech greenhouses in the Netherlands and Europe. The exposure assessment model GEM 3.3.2 (Greenhouse Emission Model 3.3.2) was used. It contains greenhouse scenarios, for both soil-less and soil-bound cultivation. Only soil-less cultivation was considered here for the use of FLU + TFS SC 500 in lettuce. A predecessor of this model or its corresponding scenarios are also mentioned in the EFSA protected crop guidance to be used for high-tech greenhouse assessments in Europe (EFSA, 2014, Appendix B, C).
The assessment was carried out for the active substance fluopyram and its metabolite trifluoroacetic acid (TFA) in soil-less cultivation in lettuce. The soil metabolite fluopyram-7-hydroxy (FLU-7-OH) was not identified in water-sediment systems and therefore no exposure assessment could be carried out for the soil-less use.

The use of fluopyram was assessed according to the Good Agricultural Practice (GAP) as summarized in Table 9.2.5-22. Substance parameters and specific GEM parameters, differing from GEM default values are summarized in Table 9.2.5- 23.

Table 9.2.5- 22: Application data of fluopyram according to use pattern in the Netherlands and Europe

Individual crop	GEM crop	Rate	Interval	BBCH stage	Application dates
		(g a.s./ha)	(days)	(-)	
Soil-less: Lettuce	Lettuce; Lactuca spp	2 × 200	7	12 - 49 (Jan - Dec)	15.01. + 22.01. 15.02. + 22.02. 15.03. + 22.03. 15.04. + 22.04. 15.05. + 22.05. 15.06. + 22.06. 15.07. + 22.07. 15.08. + 22.08. 15.09. + 22.09. 15.10. + 22.10. 15.11. + 22.11. 15.12 + 22.12. 08.04. + 15.04. 22.04. + 29.04. 08.10. + 15.10. 22.10. + 29.10.

For soil-less cultivation, spray applications were conducted at 12 dates during the year, always starting on the 15th of the month, since the growth stages in high-tech greenhouses are relatively independent of the season. Additional calculations were performed 7 days before and after the date-of-use that resulted in the highest PEC for parent and metabolite.

For the soil-less assessment, the scenarios with and without reuse of the water used for filter cleaning were chosen in the nutrient emission scenario 2018 - 2020. For both scenarios, calculations were performed with and without a mitigation removal fraction of 0.95. Consequently, four different assessments were carried out.

Table 9.2.5- 23: Substance and GEM specific parameters

Parameter	Unit	Fluopyram	Trifluoroacetic acid (TFA)
General Parameters			
Molar Mass	g/mol	396.72	114.02
Water Solubility	mg/L	19.0 (20°C)	500000 (20°C)
Vapour Pressure	Pa	1.2E-06(20°C)	1.0E-06 (20°C)
Plant uptake factor (TSCF)	-	0	0
Sorption			
Kom	mL/g	134.7	0
Freundlich Exponent		0.8432	1.0
Degradation			
Soil/Substrate	d	298.08	1000
Water	d	1000	1000
Sediment	d	1000	1000
Crop Canopy	d	10	10
Activation Energy [A]	kJ/mol	65.4	65.4
Formation fraction	-	-	Soil: 0.5402 Water: 2 Sediment: 2 Recirculation water: 2
GEM specific parameters			
Octanol-water partitioning coefficient Pow	-	2060 (log Pow = 3.3)	0.002554 (log Pow = -2.7)
Kom substrate = Kom soil	mL/g	134.7	0
DT_{50} substrate = DT_{50} soil	d	298.08	1000
DT_{50} in recirculation water / disinfection tank = DT_{50} hydrolysis	d	1000	1000
DT_{50} on greenhouse floor	d	100, default	-
DT_{50} in greenhouse air [B]	d	1.73 (=20.78 hours/12 hour days)	100
Activation Energy greenhouse air [C]	kJ/mol	45	45
Activation Energy recirculation water [D]	kJ/mol	75	75

[A] used for most DT_{50} values, i.e. soil, surface water and sediment
[B] Photochemical oxidative degradation in air
[C] used for DT_{50} greenhouse air
[D] used for DT_{50} recirculation water

Conservatively, in the very specific case of recirculation water in high-tech greenhouse systems (GEM; water and sediment) a certain potential accumulation of TFA might be assumed and therefore a maximum formation fraction of 2 was taken into account for modelling purpose.

For soil-less cultivations, the plant uptake is estimated by the transpiration stream concentration factor (TSCF) evaluated by Briggs. Briggs focused on the TSCF dependant on the octanol/water partitioning coefficient, P_{ow} or log P_{ow}, of a compound.

Fluopyram is described to be not prone to hydrolysis. Therefore, the DT_{50} in recirculation water and in disinfection tank was set to 1000 d.

Findings:

GEM PEC_{sw} results after application in soil-less cultivation with and without the reuse of filter cleaning water are summarised in Table 9.2.5- 24 and Table 9.2.5- 25. They constitute the 50th percentile of 7 annual peak concentrations. A standard mitigation of 95% can be assumed, by cleaning the discharged water.

Table 9.2.5- 24: PEC_{sw} (50th perc. of 7 annual peak concentrations) of fluopyram, 2 × 200 g/ha in lettuce in greenhouse; soil-less cultivation, no reuse of filter cleaning water

GEM scenario	Lettuce			
Mitigation (end-of-pipe reduction)	0%		95%	
Species/ Application dates	Fluopyram µg/L	TFA µg/L	Fluopyram µg/L	TFA µg/L
15.01. + 22.01.	12.36	0.461	0.600	0.023
15.02. + 22.02.	13.81	0.431	0.671	0.022
15.03. + 22.03.	15.19	0.415	0.734	0.021
15.04. + 22.04	**20.75**	0.389	**0.996**	0.020
15.05. + 22.05.	13.04	0.272	0.719	0.014
15.06. + 22.06.	9.434	0.229	0.450	0.011
15.07. + 22.07.	3.766	0.157	0.183	0.008
15.08. + 22.08.	5.394	0.191	0.254	0.010
15.09. + 22.09.	7.137	0.341	0.347	0.017
15.10. + 22.10.	6.777	**0.557**	0.330	**0.028**
15.11. + 22.11.	5.414	0.317	0.263	0.016
15.12. + 22.12.	11.29	0.546	0.548	0.027
08.04. + 15.04.	20.35	0.383	0.972	0.019
22.04. + 29.04.	16.50	0.322	0.799	0.016
08.10. + 15.10.	6.000	0.485	0.293	0.024
22.10. + 29.10.	7.547	0.468	0.366	0.024

Table 9.2.5- 25: PEC$_{sw}$ (50th perc. of 7 annual peak concentrations) of fluopyram, 2 × 200 g/ha in lettuce in greenhouse; soil-less cultivation, with reuse of filter cleaning water

GEM scenario	Lettuce			
Mitigation (end-of-pipe reduction)	0%		95%	
Species/ Application dates	Fluopyram µg/L	TFA µg/L	Fluopyram µg/L	TFA µg/L
15.01. + 22.01.	21.85	0.743	1.092	0.037
15.02. + 22.02.	21.95	0.660	1.097	0.033
15.03. + 22.03.	29.74	0.602	1.486	0.030
15.04. + 22.04	41.02	0.520	2.049	0.026
15.05. + 22.05.	36.08	0.435	1.799	0.022
15.06 + 22.06.	18.45	0.367	0.922	0.019
15.07. + 22.07.	13.30	0.272	0.662	0.014
15.08. + 22.08.	14.52	0.281	0.724	0.014
15.09. + 22.09.	21.46	0.504	1.073	0.025
15.10. + 22.10.	19.92	0.840	0.995	0.042
15.11. + 22.11.	12.36	0.458	0.612	0.023
15.12. + 22.12.	18.70	0.820	0.933	0.041
08.04. + 15.04.	41.79	0.515	2.082	0.026
22.04. + 29.04.	**43.59**	0.531	**2.178**	0.027
08.10. + 15.10.	21.17	0.735	1.058	0.037
22.10. + 29.10.	22.12	**0.895**	1.106	**0.045**

Table 9.2.5- 26 gives an overview of the GEM PEC$_{sw}$ results for handling of filter cleaning water and mitigation options. For Fluopyram application dates in April, for TFA application dates in October are leading to the maximum PEC$_{sw}$.

Table 9.2.5- 26: Maximum PEC$_{sw}$ (50th perc. of 7 annual peak concentrations) of fluopyram, 2 × 200 g/ha in lettuce in greenhouse; soil-less cultivation

Crop/ Species/ Scenario	Lettuce			
	Fluopyram		TFA	
	Application dates	µg/L	Application dates	µg/L
No reuse of filter cleaning water; 0% mitigation	15.04. + 22.04.	20.75	15.10. + 22.10.	0.557
No reuse of filter cleaning water; 95% mitigation	15.04. + 22.04.	0.996	15.10. + 22.10.	0.028
With reuse of filter cleaning water; 0% mitigation	22.04. + 29.04.	43.59	22.10. + 29.10.	0.895
With reuse of filter cleaning water; 95% mitigation	22.04. + 29.04.	2.178	22.10. + 29.10.	0.045

Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) of trifloxystrobin and its metabolites

No surface water and sediment assessment was required for trifloxystrobin and its metabolites for the renewal process of the active substance fluopyram.

CP 9.3 Fate and behaviour in air

For information on the fate and behaviour in air please refer to Document MCA, Section 7.3.

CP 9.3.1 Route and rate of degradation in air and transport via air

For information on route and rate of degradation in air and transport via air please refer to Document MCA, Sections 7.3.1 and 7.3.2.

CP 9.4 Estimation of concentrations for other routes of exposure

There are no other routes of exposure if the product is used according to good agricultural practice. Therefore no further estimations are considered necessary.