Document Title

Summary of the fate and behaviour in the environment Fluopyram SC 500 (500 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

2021-03-25

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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, Entry into Force on August 22, 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 FLU SC 500 is an SC formulation containing 500 g/kg of Fluopyram. This formulation is registered throughout Europe under trade names such as Luna Privilege. FLU SC 500 was already a representative formulation of Bayer AG for the Annex I inclusion of Fluopyram under Council Directive 91/414/EEC.

FLU SC 500 is an end use product proposed for use in the field on apples based on the application pattern shown below.

Use pattern considered in this risk assessment

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
Apple	BBCH 71-89	1	-	0.15	0.075

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})

Data Point:	KCP 9.1.3/01
Report Author:	[redacted]
Report Year:	2008
Report Title:	Predicted environmental concentrations in soil (PECsoil) for fluopyram use on tomatoes, strawberries and vines in Europe
Report No:	MEF-07/466
Document No:	M-297834-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in DAR 2011
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

This modelling report was part of the previous submission. However the modelling endpoints have been superseded by new studies and new kinetic evaluations. Consequently the report is now outdated and a summary of the results is not presented in this dossier. For procedural reasons it has to be included in the current dossier, however it is now superseded by KCP 9.1.3/03 (M-763355-01-1).

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.

[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): 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**.

Data Point:	KCP 9.1.3/03
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-763395-01-1
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 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 apples 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 apples.

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

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 [g a.s./ha]	Interval [days]	Plant Interception [%]	BBCH Stage	[g a.s./ha]
Apples	Apples	1 × 75	-	65	71 - 89	1 × 26.250

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 apples, 1 × 75 g a.s./ha, 65% interception

PEC_{soil} (mg/kg)		Apples			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.035	-	-	-
Short term	24h	0.035	0.035	-	-
	2d	0.035	0.035	-	-
	4d	0.035	0.035	-	-
Long term	7d	0.035	0.035	-	-
	14d	0.035	0.035	-	-
	21d	0.034	0.035	-	-
	28d	0.034	0.035	-	-
	42d	0.034	0.034	-	-
	50d	0.034	0.034	-	-
	100d	0.033	0.034	-	-
Plateau concentration (5 cm) after year 10		0.122	-	-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\,plateau}$)		0.157	-	-	-

Table 9.1.3- 4: PEC_{soil} for fluopyram-7-hydroxy on apples, 1 × 75 g a.s./ha, 65% interception

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

Table 9.1.3- 5: PEC_{soil} for trifluoroacetic acid on apples, 1 × 75 g a.s./ha, 65% interception

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

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
Formation fraction	-	0.6342 from parent	0.5402, overall from parent, total molar yield
Plant uptake factor TSCF	0 (Tier 1) 0.3026 (Tier 2a, Briggs)	0 (Tier 1) 0.7256 (Tier 2a, Briggs)	0 (Tier 1) 0.17 (Tier 2a, cereals)
Rate constant (1/day)	0.00233 (Tier 1), 0.00272 (Tier 2a 1), 0.0032 (Tier 2a 2)	0.03954	0.00069

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.

CP 9.2.4.1 Calculation of concentrations in groundwater

Predicted environmental concentrations in groundwater (PEC_{GW})

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

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

Data Point:	KCP 9.2.4.1/01
Report Author:	[redacted]
Report Year:	2008
Report Title:	Predicted environmental concentrations in groundwater (PECgw) for fluopyram and its metabolite AE C656948-7-hydroxy calculated with FOCUS PEARL and FOCUS PELMO - Use on tomatoes, strawberries and vines in Europe
Report No:	MEF-07/464
Document No:	M-297574-02-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in DAR 2011
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

This modelling report was part of the previous submission. However the modelling endpoints have been superseded by new studies and new kinetic evaluations. Consequently the report is now outdated and a summary of the results is not presented in this dossier. For procedural reasons it has to be included in the current dossier, however it is now superseded.

Data Point:	KCP 9.2.4.1/02
Report Author:	[redacted]
Report Year:	2012
Report Title:	FLU PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models Focus Pearl and Focus Pelmo - Use in tomatoes, strawberries and vines in Europe - Fluopyram (AE C656948) - Fluopyram-7-hydroxy
Report No:	EnSa-12/0182
Document No:	M-428665-01-1
Guideline(s) followed in study:	OPPTS 890.1100 (2009)
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in Addendum 1 to DAR 2012
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

This modelling report was part of the previous submission. However the modelling endpoints have been superseded by new studies and new kinetic evaluations. Consequently the report is now outdated and a summary of the results is not presented in this dossier. For procedural reasons it has to be included in the current dossier, however it is now superseded.

Data Point:	KCP 9.2.4.1/03
Report Author:	[redacted]
Report Year:	2012
Report Title:	Fluopyram - Peer review of new active substances - Request for additional information - Environmental fate - EFSA letter ref D(2012) HF/JS/al/620023 dated January 24, 2012
Report No:	M-428680-01-1
Document No:	M-428680-01-1
Guideline(s) followed in study:	not specified
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in Addendum 1 to DAR 2012
GLP/Officially recognised testing facilities:	not applicable
Acceptability/Reliability:	Yes

The document above was only included for transparency reasons since it was part of the first listing process. It does not contain information relevant for the current active substance renewal process.

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.

Data Point:	KCP 9.2.4.1/04
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	(-)	0.843	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	(-)	A8	A1	B1
Rate constant	(1/day)	0.00233[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 9.2.4.1/05
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 9.2.4.1/06
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 9.2.4.1/07
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 9.2.4.1/08
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-763429-01-1
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 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 9.2.4.1/10
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 9.2.4.1/11
Report Author:	Key, C.; Herrmann, M.
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 SC 500 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 apples 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)
Apples I	Apples	1 × 75	-	65	71 - 89	1 × 26.250
Apples II	Apples	1 × 75	-	65	71 - 89	1 × 26.250
Apples III	Apples	1 × 75	-	65	71 - 89	1 × 26.250

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.

[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.

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 [e)]	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.

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	Apples I	Apples II	Apples III
Repeat interval for app. events	Every year Every 2nd year Every 3rd year	Every year Every 2nd year Every 3rd year	Every year Every 2nd year Every 3rd year
Application technique	Spray	Spray	Spray
Absolute / Relative to	Absolute	Absolute	Absolute
Scenario	1st app. date (Julian day) Offset	1st app. date (Julian day) Offset	1st app. date (Julian day) Offset
Chateaudun	06 Jun (157) -	28 Jul (209) -	17 Sep (260) -
Hamburg	07 Jul (188) -	27 Aug (239) -	16 Oct (289) -
Jokioinen	01 Jun (152) -	01 Aug (213) -	01 Oct (274) -
Kremsmuenster	07 Jul (188) -	27 Aug (239) -	16 Oct (289) -
Okehampton	19 Jun (170) -	27 Jul (208) -	01 Sep (244) -
Piacenza	08 Jun (159) -	13 Aug (225) -	18 Oct (291) -
Porto	06 Jul (187) -	27 Aug (239) -	17 Oct (290) -
Sevilla	07 Jun (158) -	04 Aug (216) -	01 Oct (274) -
Thiva	06 Jul (187) -	21 Aug (233) -	06 Oct (279) -

Findings:

PEC_{gw} 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 Apples I (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception

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
Apples I	Chateaudun	0.491	0.474	0.072	0.067	2.236	2.084
	Hamburg	0.710	0.424	0.103	0.070	3.416	2.067
	Jokioinen	0.003	0.002	0.010	0.007	2.904	2.268
	Kremsmuenster	0.362	0.328	0.054	0.054	1.497	1.813
	Okehampton	0.388	0.471	0.061	0.075	1.269	1.250
	Piacenza	0.431	0.401	0.057	0.061	2.192	1.200
	Porto	0.203	0.230	0.039	0.048	0.861	0.747
	Sevilla	0.384	0.107	0.059	0.024	2.845	6.988
	Thiva	0.521	0.334	0.071	0.052	4.673	4.647
		MACRO		MACRO		MACRO	
	Châteaudun	0.101		0.013		6.350	

Table 9.2.4.1- 7: Tier 1 PEC_{gw} for fluopyram and its metabolites on Apples II (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception

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
Apples II	Chateaudun	0.497	0.474	0.073	0.067	2.220	2.079
	Hamburg	0.739	0.447	0.107	0.074	3.413	2.046
	Jokioinen	0.003	0.002	0.011	0.007	2.823	2.253
	Kremsmuenster	0.370	0.348	0.055	0.055	1.491	1.824
	Okehampton	0.401	0.485	0.063	0.076	1.260	1.243
	Piacenza	0.481	0.422	0.064	0.064	2.204	1.207
	Porto	0.215	0.243	0.041	0.049	0.856	0.767
	Sevilla	0.373	0.100	0.058	0.022	2.841	6.987
	Thiva	0.523	0.335	0.071	0.049	4.728	4.588
		MACRO		MACRO		MACRO	
	Châteaudun	0.115		0.014		5.933	

Table 9.2.4.1- 8: Tier 1 PEC_{gw} for fluopyram and its metabolites on Apples III (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception

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
Apples III	Chateaudun	0.511	0.497	0.075	0.070	2.221	2.070
	Hamburg	0.744	0.456	0.108	0.075	3.383	2.035
	Jokioinen	0.003	0.002	0.011	0.007	2.747	2.251
	Kremsmuenster	0.373	0.353	0.056	0.056	1.486	1.834
	Okehampton	0.420	0.314	0.065	0.080	1.254	1.240
	Piacenza	0.484	0.445	0.064	0.067	2.161	1.252
	Porto	0.218	0.260	0.041	0.053	0.854	0.763
	Sevilla	0.389	0.127	0.060	0.027	2.857	6.913
	Thiva	0.545	0.414	0.074	0.059	4.773	4.656
		MACRO		MACRO		MACRO	
	Châteaudun	0.118		0.015		6.340	

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

Annual application

Table 9.2.4.1- 9: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Apples I (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples I	Chateaudun	0.173	0.130	0.032	0.027	2.188	1.963
	Hamburg	0.225	0.102	0.041	0.028	3.242	1.901
	Jokioinen	<0.001	<0.001	0.001	0.002	2.549	2.118
	Kremsmuenster	0.118	0.070	0.023	0.019	1.471	1.726
	Okehampton	0.186	0.204	0.038	0.043	1.273	1.199
	Piacenza	0.160	0.192	0.026	0.038	2.145	1.155
	Porto	0.090	0.096	0.024	0.027	0.845	0.694
	Sevilla	0.113	0.008	0.023	0.003	2.708	6.202
	Thiva	0.173	0.056	0.030	0.014	4.509	4.140
		MACRO		MACRO		MACRO	
	Chateaudun	<0.001		<0.001		6.014	

Table 9.2.4.1- 10: Tier 2a 1 PEC$_{gw}$ for fluopyram and its metabolites on Apples II (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples II	Chateaudun	0.174	0.126	0.032	0.027	2.194	1.952
	Hamburg	0.235	0.106	0.043	0.029	3.239	1.885
	Jokioinen	<0.001	<0.001	0.001	<0.002	2.470	2.103
	Kremsmuenster	0.120	0.071	0.024	0.019	1.465	1.729
	Okehampton	0.188	0.206	0.039	0.044	1.265	1.191
	Piacenza	0.178	0.201	0.028	0.038	2.167	1.151
	Porto	0.094	0.099	0.025	0.028	0.844	0.717
	Sevilla	0.110	0.007	0.023	0.003	2.715	6.136
	Thiva	0.173	0.048	0.030	0.013	4.556	4.058
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		5.666	

Table 9.2.4.1- 11: Tier 2a 1 PEC$_{gw}$ for fluopyram and its metabolites on Apples III (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples III	Chateaudun	0.179	0.128	0.033	0.027	2.202	1.932
	Hamburg	0.237	0.105	0.043	0.029	3.208	1.878
	Jokioinen	<0.001	<0.001	0.001	0.002	2.400	2.089
	Kremsmuenster	0.124	0.073	0.024	0.019	1.461	1.733
	Okehampton	0.197	0.218	0.040	0.046	1.260	1.188
	Piacenza	0.180	0.208	0.028	0.039	2.128	1.187
	Porto	0.097	0.109	0.026	0.030	0.840	0.717
	Sevilla	0.114	0.008	0.023	0.003	2.720	5.995
	Thiva	0.183	0.062	0.031	0.016	4.604	4.075
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		6.097	

Biennial application

Table 9.2.4.1- 12: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Apples I (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples I	Chateaudun	0.063	0.051	0.013	0.012	1.024	1.007
	Hamburg	0.099	0.063	0.020	0.016	1.746	0.908
	Jokioinen	<0.001	0.001	0.002	0.002	1.722	1.382
	Kremsmuenster	0.048	0.037	0.011	0.010	0.827	0.945
	Okehampton	0.069	0.079	0.016	0.019	0.524	0.516
	Piacenza	0.056	0.069	0.010	0.015	2.092	0.599
	Porto	0.030	0.033	0.009	0.012	0.374	0.366
	Sevilla	0.035	0.004	0.009	0.002	1.854	2.941
	Thiva	0.057	0.018	0.012	0.006	1.699	1.954
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		3.653	

Table 9.2.4.1- 13: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Apples II (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples II	Chateaudun	0.064	0.050	0.013	0.012	1.015	1.025
	Hamburg	0.103	0.067	0.021	0.017	1.749	0.905
	Jokioinen	<0.001	0.001	0.002	0.002	1.731	1.419
	Kremsmuenster	0.048	0.038	0.011	0.010	0.828	0.967
	Okehampton	0.069	0.079	0.016	0.019	0.528	0.517
	Piacenza	0.063	0.074	0.012	0.016	2.117	0.602
	Porto	0.032	0.035	0.010	0.012	0.376	0.368
	Sevilla	0.035	0.003	0.009	0.002	1.823	2.953
	Thiva	0.056	0.016	0.012	0.005	1.715	1.880
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		3.350	

Table 9.2.4.1- 14: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Apples III (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples III	Chateaudun	0.065	0.051	0.014	0.012	1.018	1.055
	Hamburg	0.103	0.067	0.021	0.017	1.752	0.900
	Jokioinen	<0.001	0.001	0.002	0.002	1.732	1.452
	Kremsmuenster	0.049	0.039	0.011	0.010	0.828	0.967
	Okehampton	0.072	0.084	0.017	0.020	0.526	0.512
	Piacenza	0.065	0.076	0.012	0.017	2.145	0.597
	Porto	0.032	0.038	0.010	0.013	0.379	0.373
	Sevilla	0.035	0.004	0.009	0.003	1.807	2.905
	Thiva	0.060	0.021	0.012	0.006	1.707	1.878
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		3.641	

Triennial application

Table 9.2.4.1- 15: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Apples I (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples I	Chateaudun	0.053	0.027	0.008	0.007	0.700	0.718
	Hamburg	0.053	0.033	0.012	0.009	0.925	0.566
	Jokioinen	0.002	0.003	0.002	0.002	0.891	0.769
	Kremsmuenster	0.025	0.019	0.006	0.005	0.567	0.574
	Okehampton	0.037	0.043	0.009	0.011	0.357	0.343
	Piacenza	0.031	0.039	0.006	0.009	1.641	0.367
	Porto	0.015	0.017	0.005	0.006	0.235	0.236
	Sevilla	0.017	0.002	0.005	0.001	1.004	1.820
	Thiva	0.029	0.009	0.007	0.003	1.350	1.401
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		2.364	

Table 9.2.4.1- 16: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Apples II (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples II	Chateaudun	0.033	0.026	0.008	0.007	0.706	0.724
	Hamburg	0.055	0.035	0.012	0.010	0.918	0.559
	Jokioinen	0.002	0.003	0.002	0.002	0.868	0.773
	Kremsmuenster	0.026	0.019	0.006	0.006	0.578	0.583
	Okehampton	0.039	0.044	0.009	0.011	0.359	0.346
	Piacenza	0.034	0.040	0.007	0.010	1.650	0.373
	Porto	0.016	0.018	0.006	0.007	0.236	0.236
	Sevilla	0.017	0.002	0.005	0.001	0.998	1.803
	Thiva	0.029	0.008	0.006	0.003	1.326	1.356
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		2.106	

Table 9.2.4.1- 17: Tier 2a 1 PEC_{gw} for fluopyram and its metabolites on Apples III (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples III	Chateaudun	0.034	0.027	0.008	0.007	0.702	0.721
	Hamburg	0.056	0.036	0.012	0.010	0.915	0.561
	Jokioinen	0.002	0.003	0.002	0.002	0.862	0.765
	Kremsmuenster	0.027	0.020	0.006	0.006	0.591	0.594
	Okehampton	0.040	0.046	0.010	0.012	0.361	0.347
	Piacenza	0.033	0.041	0.007	0.010	1.685	0.379
	Porto	0.016	0.019	0.006	0.007	0.238	0.238
	Sevilla	0.017	0.002	0.005	0.001	0.992	1.795
	Thiva	0.030	0.010	0.007	0.003	1.318	1.374
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		2.359	

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

Annual application

Table 9.2.4.1- 18: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples I (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples I	Chateaudun	0.085	0.061	0.021	0.018	2.229	2.005
	Hamburg	0.124	0.052	0.031	0.020	3.387	1.982
	Jokioinen	<0.001	<0.001	<0.001	<0.001	2.768	2.176
	Kremsmuenster	0.059	0.032	0.016	0.012	1.497	1.787
	Okehampton	0.101	0.125	0.029	0.033	1.299	1.231
	Piacenza	0.078	0.114	0.018	0.031	2.170	1.176
	Porto	0.044	0.050	0.017	0.020	0.859	0.702
	Sevilla	0.052	0.002	0.015	0.002	2.756	6.349
	Thiva	0.082	0.020	0.021	0.008	4.575	4.208
		MACRO		MACRO		MACRO	
	Chateaudun	<0.001		<0.001		6.033	

Table 9.2.4.1- 19: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples II (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples II	Chateaudun	0.086	0.059	0.021	0.017	2.227	1.996
	Hamburg	0.131	0.055	0.032	0.022	3.392	1.963
	Jokioinen	<0.001	<0.001	<0.001	<0.001	2.689	2.162
	Kremsmuenster	0.060	0.033	0.016	0.013	1.490	1.763
	Okehampton	0.103	0.117	0.029	0.034	1.290	1.223
	Piacenza	0.088	0.119	0.020	0.032	2.198	1.172
	Porto	0.047	0.052	0.018	0.021	0.858	0.730
	Sevilla	0.050	0.002	0.015	0.002	2.763	6.281
	Thiva	0.081	0.017	0.020	0.007	4.633	4.135
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		5.712	

Table 9.2.4.1- 20: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples III (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples III	Chateaudun	0.089	0.060	0.022	0.018	2.237	1.976
	Hamburg	0.133	0.055	0.033	0.022	3.361	1.943
	Jokioinen	<0.001	<0.001	<0.001	0.001	2.601	2.149
	Kremsmuenster	0.064	0.034	0.016	0.013	1.482	1.769
	Okehampton	0.109	0.125	0.031	0.036	1.286	1.221
	Piacenza	0.092	0.125	0.021	0.033	2.154	1.217
	Porto	0.049	0.059	0.019	0.023	0.854	0.736
	Sevilla	0.053	0.003	0.015	0.002	2.771	6.149
	Thiva	0.087	0.023	0.022	0.009	4.688	4.153
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		6.122	

Biennial application

Table 9.2.4.1- 21: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples I (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, biennial application, 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
Apples I	Chateaudun	0.028	0.022	0.008	0.007	1.033	1.020
	Hamburg	0.050	0.030	0.015	0.011	1.770	0.945
	Jokioinen	<0.001	0.001	0.001	0.001	1.729	1.407
	Kremsmuenster	0.021	0.015	0.007	0.006	0.835	0.959
	Okehampton	0.035	0.042	0.011	0.014	0.537	0.528
	Piacenza	0.026	0.038	0.007	0.012	2.114	0.609
	Porto	0.013	0.016	0.006	0.009	0.378	0.373
	Sevilla	0.014	0.001	0.005	0.001	1.877	3.003
	Thiva	0.025	0.006	0.007	0.003	1.713	1.995
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		3.668	

Table 9.2.4.1- 22: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples II (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples II	Chateaudun	0.028	0.021	0.008	0.007	1.023	1.041
	Hamburg	0.053	0.032	0.015	0.012	1.773	0.944
	Jokioinen	<0.001	0.001	0.001	0.001	1.740	1.451
	Kremsmuenster	0.021	0.016	0.007	0.006	0.837	0.985
	Okehampton	0.035	0.041	0.012	0.014	0.538	0.529
	Piacenza	0.031	0.041	0.008	0.012	2.137	0.613
	Porto	0.014	0.017	0.007	0.009	0.381	0.376
	Sevilla	0.014	0.001	0.005	0.001	1.844	3.012
	Thiva	0.024	0.005	0.007	0.003	1.733	1.922
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		3.389	

Table 9.2.4.1- 23: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples III (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples III	Chateaudun	0.029	0.022	0.009	0.007	1.033	1.078
	Hamburg	0.053	0.032	0.015	0.012	1.776	0.940
	Jokioinen	<0.001	0.001	0.001	0.001	1.742	1.492
	Kremsmuenster	0.022	0.016	0.007	0.006	0.836	0.987
	Okehampton	0.037	0.045	0.012	0.015	0.538	0.525
	Piacenza	0.031	0.043	0.008	0.013	2.170	0.608
	Porto	0.014	0.019	0.007	0.010	0.385	0.381
	Sevilla	0.014	0.001	0.005	0.001	1.827	2.970
	Thiva	0.027	0.007	0.008	0.004	1.725	1.908
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		3.645	

Triennial application

Table 9.2.4.1- 24: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples I (with FOCUS PEARL/ PELMO/ MACRO) – 1 ×75 g a.s./ha, 65% interception, 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
Apples I	Chateaudun	0.014	0.011	0.005	0.004	0.704	0.725
	Hamburg	0.026	0.015	0.008	0.006	0.935	0.587
	Jokioinen	<0.001	0.001	<0.001	0.001	0.909	0.781
	Kremsmuenster	0.010	0.007	0.004	0.003	0.569	0.576
	Okehampton	0.018	0.022	0.006	0.008	0.361	0.348
	Piacenza	0.013	0.020	0.004	0.007	1.651	0.370
	Porto	0.006	0.008	0.003	0.004	0.237	0.238
	Sevilla	0.006	0.001	0.003	0.001	1.011	1.867
	Thiva	0.012	0.003	0.004	0.002	1.365	1.426
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		2.371	

Table 9.2.4.1- 25: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples II (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples II	Chateaudun	0.014	0.011	0.005	0.004	0.709	0.729
	Hamburg	0.027	0.016	0.008	0.007	0.927	0.580
	Jokioinen	<0.001	0.001	<0.001	0.001	0.905	0.786
	Kremsmuenster	0.011	0.008	0.004	0.003	0.576	0.586
	Okehampton	0.019	0.022	0.007	0.008	0.362	0.352
	Piacenza	0.015	0.021	0.004	0.007	1.659	0.376
	Porto	0.007	0.008	0.004	0.005	0.238	0.239
	Sevilla	0.006	0.001	0.003	0.001	1.004	1.852
	Thiva	0.012	0.003	0.004	0.001	1.337	1.381
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		2.128	

Table 9.2.4.1- 26: Tier 2a 2 PEC_{gw} for fluopyram and its metabolites on Apples III (with FOCUS PEARL/ PELMO/ MACRO) – 1 × 75 g a.s./ha, 65% interception, 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
Apples III	Chateaudun	0.014	0.011	0.005	0.004	0.706	0.730
	Hamburg	0.028	0.017	0.009	0.007	0.924	0.573
	Jokioinen	0.001	0.001	<0.001	0.001	0.905	0.778
	Kremsmuenster	0.014	0.008	0.004	0.003	0.590	0.599
	Okehampton	0.020	0.024	0.007	0.009	0.365	0.353
	Piacenza	0.015	0.022	0.004	0.008	1.697	0.384
	Porto	0.007	0.009	0.004	0.005	0.240	0.241
	Sevilla	0.006	0.001	0.003	0.001	0.998	1.825
	Thiva	0.012	0.003	0.004	0.002	1.327	1.402
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		2.362	

Conclusion:

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

In Table 9.2.4.1- 27 to Table 9.2.4.1- 47 the maximum PEC_{gw} values of fluopyram and its metabolites for FOCUS PEARL/ PELMO/ MACRO calculations for all use patterns in apples are given at Tier 1 (Table 9.2.4.1- 27 to Table 9.2.4.1- 29), Tier 2a 1 (Table 9.2.4.1- 30 to Table 9.2.4.1- 38), and Tier 2a 2 (Table 9.2.4.1- 39 to Table 9.2.4.1- 47).

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

Table 9.2.4.1- 27: 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
Apples I, 1×75 g a.s./ha	0.710	0.103	4.673
Apples II, 1×75 g a.s./ha	0.739	0.107	4.728
Apples III, 1×75 g a.s./ha	0.744	0.108	4.773

Table 9.2.4.1- 28: 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
Apples I, 1×75 g a.s./ha	0.474	0.075	6.988
Apples II, 1×75 g a.s./ha	0.485	0.076	6.987
Apples III, 1×75 g a.s./ha	0.514	0.080	6.913

Table 9.2.4.1- 29: 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
Apples I, 1×75 g a.s./ha	0.101	0.013	6.350
Apples II, 1×75 g a.s./ha	0.115	0.014	5.933
Apples III, 1×75 g a.s./ha	0.118	0.015	6.340

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

Annual application

Table 9.2.4.1- 30: 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
Apples I, 1×75 g a.s./ha	0.225	0.041	4.509
Apples II, 1×75 g a.s./ha	0.235	0.043	4.556
Apples III, 1×75 g a.s./ha	0.237	0.043	4.604

Table 9.2.4.1- 31: 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
Apples I, 1×75 g a.s./ha	0.204	0.043	6.202
Apples II, 1×75 g a.s./ha	0.206	0.044	6.136
Apples III, 1×75 g a.s./ha	0.218	0.046	5.995

Table 9.2.4.1- 32: 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
Apples I, 1×75 g a.s./ha	<0.001	<0.001	6.014
Apples II, 1×75 g a.s./ha	<0.001	<0.001	5.666
Apples III, 1×75 g a.s./ha	<0.001	<0.001	6.097

Biennial application

Table 9.2.4.1- 33: 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
Apples I, 1×75 g a.s./ha	0.099	0.020	2.092
Apples II, 1×75 g a.s./ha	0.103	0.021	2.117
Apples III, 1×75 g a.s./ha	0.103	0.021	2.145

Table 9.2.4.1- 34: 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
Apples I, 1×75 g a.s./ha	0.079	0.019	2.941
Apples II, 1×75 g a.s./ha	0.079	0.019	2.953
Apples III, 1×75 g a.s./ha	0.084	0.020	2.905

Table 9.2.4.1- 35: 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
Apples I, 1×75 g a.s./ha	<0.001	<0.001	3.653
Apples II, 1×75 g a.s./ha	<0.001	<0.001	3.350
Apples III, 1×75 g a.s./ha	<0.001	<0.001	3.641

Triennial application

Table 9.2.4.1- 36: 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
Apples I, 1×75 g a.s./ha	0.053	0.012	1.641
Apples II, 1×75 g a.s./ha	0.055	0.012	1.650
Apples III, 1×75 g a.s./ha	0.056	0.012	1.685

Table 9.2.4.1- 37: 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
Apples I, 1×75 g a.s./ha	0.043	0.011	1.820
Apples II, 1×75 g a.s./ha	0.044	0.011	1.803
Apples III, 1×75 g a.s./ha	0.046	0.012	1.795

Table 9.2.4.1- 38: 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
Apples I, 1×75 g a.s./ha	<0.001	<0.001	2.364
Apples II, 1×75 g a.s./ha	<0.001	<0.001	2.106
Apples III, 1×75 g a.s./ha	<0.001	<0.001	2.359

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

Annual application

Table 9.2.4.1- 39: 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
Apples I, 1×75 g a.s./ha	0.124	0.031	4.575
Apples II, 1×75 g a.s./ha	0.131	0.032	4.633
Apples III, 1×75 g a.s./ha	0.133	0.033	4.688

Table 9.2.4.1- 40: 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
Apples I, 1×75 g a.s./ha	0.115	0.033	6.349
Apples II, 1×75 g a.s./ha	0.119	0.034	6.281
Apples III, 1×75 g a.s./ha	0.125	0.036	6.149

Table 9.2.4.1- 41: 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
Apples I, 1×75 g a.s./ha	<0.001	<0.001	6.033
Apples II, 1×75 g a.s./ha	<0.001	<0.001	5.712
Apples III, 1×75 g a.s./ha	<0.001	<0.001	6.122

Biennial application

Table 9.2.4.1- 42: Maximum FOCUS PEARL 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
Apples I, 1×75 g a.s./ha	0.050	0.015	2.114
Apples II, 1×75 g a.s./ha	0.053	0.015	2.137
Apples III, 1×75 g a.s./ha	0.053	0.015	2.170

Table 9.2.4.1- 43: 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
Apples I, 1×75 g a.s./ha	0.042	0.014	3.003
Apples II, 1×75 g a.s./ha	0.041	0.014	3.012
Apples III, 1×75 g a.s./ha	0.045	0.015	2.970

Table 9.2.4.1- 44: 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
Apples I, 1×75 g a.s./ha	<0.001	<0.001	3.668
Apples II, 1×75 g a.s./ha	<0.001	<0.001	3.389
Apples III, 1×75 g a.s./ha	<0.001	<0.001	3.645

Triennial application

Table 9.2.4.1- 45: Maximum FOCUS PEARL 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
Apples I, 1×75 g a.s./ha	0.026	0.008	1.651
Apples II, 1×75 g a.s./ha	0.027	0.008	1.659
Apples III, 1×75 g a.s./ha	0.028	0.009	1.697

Table 9.2.4.1- 46: 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
Apples I, 1×75 g a.s./ha	0.022	0.008	1.867
Apples II, 1×75 g a.s./ha	0.022	0.008	1.852
Apples III, 1×75 g a.s./ha	0.024	0.009	1.825

Table 9.2.4.1- 47: 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
Apples I, 1×75 g a.s./ha	<0.001	<0.001	2.371
Apples II, 1×75 g a.s./ha	<0.001	<0.001	2.128
Apples III, 1×75 g a.s./ha	<0.001	<0.001	2.362

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**

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)	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°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 fraciton 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.

Data Point:	KCP 9.2.5/04
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 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	17.53	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 Step 3 level

Parameter	Unit	Parent	Metabolite	Metabolite
Substance		Fluopyram_Tier 1	FLU-7-hydroxy_Tier1	TFA_Tier 1
SWASH code		FLU	7OH	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	100.2	0
K_{OM}	(mL/g)	134.7	58.1	0
Freundlich exponent ($^1/_n$)	(-)	0.8432	0.9292	1
Transformation				
DT50 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
DT50 in water	(days)	1000	1000	1000
temperature	(°C)	20	20	20
formation fraction in water	(-)	-	-	-
DT50 in sediment	(days)	1000	1000	1000
temperature	(°C)	20	20	20
formation fraction in sediment	(-)	-	-	-
DT50 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.

Data Point:	KCP 9.2.5/01
Report Author:	[redacted]
Report Year:	2008
Report Title:	Predicted environmental concentrations in surface water and sediment (PECsw, PECsed) of Fluopyram calculated according FOCUS - use on fruiting vegetables and vines in Europe
Report No:	MEF-07/465
Document No:	M-297592-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in DAR 2011
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

This modelling report was part of the previous submission. However the modelling endpoints have been superseded by new studies and new kinetic evaluations. Consequently the report is now outdated and a summary of the results is not presented in this dossier. For procedural reasons it has to be included in the current dossier, however it is now superseded.

Data Point:	KCP 9.2.5/02
Report Author:	[redacted]
Report Year:	2013
Report Title:	FLU PECsw FOCUS EUR: Predicted environmental concentrations in surface water and sediment - Use in fruiting vegetables, e.g. tomatoes and strawberries, and vines in Europe - Fluopyram (AE C656948)
Report No:	Ens-12-0183
Document No:	M-428666-01-1
Guideline(s) followed in study:	OPPTS 890.1100 (2009)
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in Addendum 1 to DAR 2012
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

This modelling report was part of the previous submission. However the modelling endpoints have been superseded by new studies and new kinetic evaluations. Consequently the report is now outdated and a summary of the results is not presented in this dossier. For procedural reasons it has to be included in the current dossier, however it is now superseded.

Data Point:	KCP 9.2.5/03
Report Author:	[redacted]
Report Year:	2012
Report Title:	Fluopyram - Peer review of new active substances - Request for additional information - Environmental fate - EFSA letter ref D(2012)CHF/JS/al/620079, dated January 24, 2012
Report No:	M-428680-01-1
Document No:	M-428680-01-1
Guideline(s) followed in study:	not specified
Deviations from current test guideline:	Current guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in Addendum 1 to DAR 2012
GLP/Officially recognised testing facilities:	not applicable
Acceptability/Reliability:	Yes

The document above was only included for transparency reasons since it was part of the first listing process. It does not contain information relevant for the current active substance renewal process.

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 9.2.5/05
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 9.2.5/06
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 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 apples (FOCUS crop: pome/stone fruit, 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
Apples	71 - 89	1 × 75		Pome / stone fruit, late applications (fruit crops / late)	Autumn (Oct. - Feb.) Summer (Jun. - Sep.)	Full canopy

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

For the uses in apples 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	Apple, early		Apple, 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.	1		1	
PAT window range	30		30	
Appl. interval	-		-	
Scenarios	PAT start/end date (Julian day)	Application date	PAT start/end date (Julian day)	Application date
D3 Ditch	07-Jul/06-Aug (188/218)	08-Jul	16-Oct/15-Nov (289/319)	18-Oct
D4 Pond/Stream	11-Jul/10-Aug (192/222)	11-Jul	16-Oct/15-Nov (289/319)	26-Oct
D5 Pond/Stream	07-Jun/07-Jul (158/188)	09-Jun	26-Sep/26-Oct (269/299)	26-Sep
R1 Pond/Stream	07-Jul/06-Aug (188/218)	11-Jul	16-Oct/15-Nov (289/319)	19-Oct
R2 Stream	03-Aug/02-Sep (215/245)	05-Aug	16-Sep/16-Oct (259/289)	09-Oct
R3 Stream	07-Jun/07-Jul (158/188)	23-Jun	01-Oct/31-Oct (274/304)	01-Oct
R4 Stream	07-Jun/07-Jul (158/188)	08-Jun	01-Oct/31-Oct (274/304)	18-Oct

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 apples (FOCUS crop: apple).

Fluopyram

Table 9.2.5- 6: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for fluopyram following single application(s) of FLU SC 500 to apples (modelling use apple -- autumn -- 1×75 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	23.0	RunOff	21.9	51.2
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	6.56 *	Drift	6.26	14.6 *
Southern Europe	Oct. - Feb. (Autumn)	5.90 *	Drift	5.60	13.1 *

* 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 application(s) of FLU SC 500 to apples (modelling use apple -- summer -- 1×75 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1		23.0	RunOff	21.9	51.2
Step 2					
Northern Europe	Jun. - Sep. (Summer)	4.57 *	Drift	4.29	10.0 *
Southern Europe	Jun. - Sep. (Summer)	5.24 *	Drift	4.95	11.5 *

* 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 application(s) of FLU SC 500 to apples (modelling use apple -- autumn -- 1×75 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	1.33	-	1.32	1.33
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	0.232 *	-	0.231	0.233 *
Southern Europe	Oct. - Feb. (Autumn)	0.186 *	-	0.184	0.186 *

* 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 application(s) of FLU SC 500 to apples (modelling use apple -- summer -- 1×75 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	1.33	-	1.32	1.33
Step 2					
Northern Europe	Jun. - Sep. (Summer)	0.093 *	-	0.092	0.093 *
Southern Europe	Jun. - Sep. (Summer)	0.139 *	-	0.138	0.140 *

* 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 application(s) of FLU SC 500 to apples (modelling use apple -- autumn -- 1×75 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1		1.06	-	1.06	<0.001
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	0.186 *	-	0.184	<0.001 *
Southern Europe	Oct. - Feb. (Autumn)	0.149 *	-	0.147	<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 application(s) of FLU SC 500 to apples (modelling use apple -- summer -- 1×75 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	1.06	-	1.06	<0.001
Step 2					
Northern Europe	Jun. - Sep. (Summer)	0.074 *		0.074	<0.001 *
Southern Europe	Jun. - Sep. (Summer)	0.111 *	-	0.111	<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 apples (FOCUS crop: pome/stone fruit, 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 application(s) of FLU SC 500 to apples (modelling use apple -- early -- 0.075 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D3	Ditch	2.76 *	Spray drift	0.265	1.51 *
D4	Pond	0.681 *	Drainage	0.631	3.41 *
D4	Stream	2.77 *	Spray drift	0.419	1.19 *
D5	Pond	0.423 *	Drainage	0.408	3.74 *
D5	Stream	2.98 *	Spray drift	0.148	0.954 *
R1	Pond	0.123 *	Spray drift	0.106	0.511 *
R1	Stream	2.07 *	Spray drift	0.021	0.182 *
R2	Stream	2.84 *	Spray drift	0.015	0.211 *
R3	Stream	2.98 *	Spray drift	0.053	0.619 *
R4	Stream	2.12 *	Spray drift	0.086	0.532 *

* 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 application(s) of FLU SC 500 to apples (modelling use apple -- late -- 0.075 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D3	Ditch	2.76 *	Spray drift	0.294	1.59 *
D4	Pond	0.573 *	Drainage	0.555	2.91 *
D4	Stream	2.64 *	Spray drift	0.350	1.92 *
D5	Pond	0.783 *	Drainage	0.758	5.10 *
D5	Stream	2.98 *	Spray drift	0.365	1.09 *
R1	Pond	0.123 *	Spray drift	0.106	0.516 *
R1	Stream	2.12 *	Spray drift	0.021	0.288 *
R2	Stream	2.84 *	Spray drift	0.034	0.300 *
R3	Stream	2.98 *	Spray drift	0.077	0.619 *
R4	Stream	1.90 *	Spray drift	0.029	0.234 *

* 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 application(s) of FLU SC 500 to apples (modelling use apple -- early -- 0.075 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D3	Ditch	<0.001 *	-	<0.001	<0.001 *
D4	Pond	0.042 *	-	0.041	0.117 *
D4	Stream	0.046 *	-	0.027	0.039 *
D5	Pond	0.044 *	-	0.043	0.181 *
D5	Stream	0.034 *	-	0.015	0.039 *
R1	Pond	<0.001 *	-	<0.001	<0.001 *
R1	Stream	0.002 *	-	<0.001	<0.001 *
R2	Stream	0.009 *	-	<0.001	0.003 *
R3	Stream	0.020 *	-	0.001	0.006 *
R4	Stream	0.009 *	-	<0.001	0.003 *

* 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 application(s) of FLU SC 500 to apples (modelling use apple -- late -- 0.075 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D3	Ditch	<0.001 *	-	<0.001	<0.001 *
D4	Pond	0.036 *	-	0.035	0.098 *
D4	Stream	0.039 *	-	0.023	0.033 *
D5	Pond	0.040 *	-	0.038	0.170 *
D5	Stream	0.061 *	-	0.017	0.033 *
R1	Pond	<0.001 *	-	<0.001	<0.001 *
R1	Stream	<0.001 *	-	<0.001	<0.001 *
R2	Stream	0.008 *	-	<0.001	0.003 *
R3	Stream	0.004 *	-	<0.001	0.001 *
R4	Stream	0.001 *	-	<0.001	<0.001 *

* 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 application(s) of FLU SC 500 to apples (modelling use apple -- early -- 0.075 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D3	Ditch	0.793 *	-	0.792	0.516 *
D4	Pond	0.948 *	-	0.943	0.561 *
D4	Stream	0.439 *	-	0.402	0.216 *
D5	Pond	1.30 *	-	1.29	0.816 *
D5	Stream	0.539 *	-	0.511	0.243 *
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	0.012 *	-	<0.001	<0.001 *
R4	Stream	0.002 *	-	<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 application(s) of FLU SC 500 to apples (modelling use apple -- late -- 0.075 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D3	Ditch	0.643 *	-	0.643	0.431 *
D4	Pond	0.848 *	-	0.844	0.492 *
D4	Stream	0.415 *	-	0.373	0.189 *
D5	Pond	1.02 *	-	1.01	0.627 *
D5	Stream	0.400 *	-	0.346	0.185 *
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	<0.001 *	-	<0.001	<0.001 *
R4	Stream	<0.001 *	-	<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 apples (FOCUS crop: pome/stone fruit, 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 application of FLU SC 500 to apples according to surface water Step 4 (modelling use apple -- early -- 0.075 kg a.s./ha)

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	D3 Ditch	2.76	1.86	0.832	0.257	0.832	0.257		
50 %		1.38	0.930	0.416	0.128	0.416	0.128		
75 %		0.689	0.465	0.208	0.064	0.208	0.064		
90 %		0.276	0.186	0.083	0.026	0.083	0.026		
None	D4 Pond	0.651	0.655	0.638	0.627	0.638	0.627		
50 %		0.634	0.636	0.628	0.622	0.628	0.622		
75 %		0.626	0.627	0.623	0.620	0.623	0.620		
90 %		0.621	0.621	0.619	0.618	0.619	0.618		
None	D4 Stream	2.77	2.16	0.965	0.669	0.965	0.669		

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		
50 %		1.38	1.08	0.669	0.669	0.669	0.669		
75 %		0.692	0.669	0.669	0.669	0.669	0.669		
90 %		0.669	0.669	0.669	0.669	0.669	0.669		
None	D5 Pond	0.423	0.427	0.415	0.406	0.415	0.406		
50 %		0.411	0.413	0.407	0.403	0.407	0.403		
75 %		0.405	0.406	0.403	0.401	0.403	0.401		
90 %		0.402	0.402	0.401	0.400	0.401	0.400		
None	D5 Stream	2.99	2.33	1.04	0.377	1.04	0.377		
50 %		1.49	1.17	0.520	0.377	0.520	0.377		
75 %		0.746	0.582	0.377	0.377	0.377	0.377		
90 %		0.377	0.377	0.377	0.377	0.377	0.377		
None	R1 Pond	0.123	0.141	0.078	0.036	0.078	0.036		
50 %		0.062	0.071	0.039	0.018	0.039	0.018		
75 %		0.031	0.035	0.020	0.010	0.020	0.009		
90 %		0.013	0.014	0.009	0.005	0.008	0.004		
None	R1 Stream	2.07	1.62	0.723	0.364	0.723	0.223		
50 %		1.04	0.809	0.364	0.364	0.362	0.112		
75 %		0.518	0.405	0.364	0.364	0.181	0.078		
90 %		0.364	0.364	0.364	0.364	0.153	0.078		
None	R2 Stream	2.84	2.21	0.989	0.305	0.989	0.305		
50 %		1.42	1.11	0.495	0.153	0.495	0.153		
75 %		0.709	0.553	0.247	0.152	0.247	0.076		
90 %		0.284	0.221	0.152	0.152	0.099	0.036		
None	R3 Stream	2.98	2.33	1.04	0.336	1.04	0.321		
50 %		1.49	1.16	0.520	0.336	0.520	0.161		
75 %		0.746	0.582	0.336	0.336	0.260	0.080		
90 %		0.336	0.336	0.336	0.336	0.149	0.077		
None	R4 Stream	2.12	1.65	1.08	1.08	0.738	0.243		
50 %		1.08	1.08	1.08	1.08	0.471	0.243		
75 %		1.08	1.08	1.08	1.08	0.471	0.243		
90 %		1.08	1.08	1.08	1.08	0.471	0.243		

Table 9.2.5- 19: PEC_{sw} values for fluopyram, following single application of FLU SC 500 to apples according to surface water Step 4 (modelling use apple -- late -- 0.075 kg a.s./ha)

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	D3 Ditch	2.76	1.86	0.832	0.257	0.832	0.257		
50 %		1.38	0.931	0.416	0.128	0.416	0.128		
75 %		0.690	0.465	0.208	0.064	0.208	0.064		
90 %		0.276	0.186	0.083	0.026	0.083	0.026		
None	D4 Pond	0.573	0.581	0.552	0.534	0.552	0.534		
50 %		0.545	0.549	0.535	0.526	0.535	0.526		
75 %		0.531	0.533	0.526	0.522	0.526	0.522		
90 %		0.523	0.524	0.521	0.519	0.521	0.519		
None	D4 Stream	2.64	2.06	0.921	0.579	0.921	0.579		
50 %		1.32	1.03	0.579	0.579	0.579	0.579		
75 %		0.660	0.579	0.579	0.579	0.579	0.579		
90 %		0.579	0.579	0.579	0.579	0.579	0.579		
None	D5 Pond	0.783	0.783	0.783	0.783	0.783	0.783		
50 %		0.783	0.783	0.783	0.783	0.783	0.783		
75 %		0.783	0.783	0.783	0.783	0.783	0.783		
90 %		0.783	0.783	0.783	0.783	0.783	0.783		
None	D5 Stream	2.98	2.33	1.14	1.14	1.14	1.14		
50 %		1.49	1.17	1.14	1.14	1.14	1.14		
75 %		1.14	1.14	1.14	1.14	1.14	1.14		
90 %		1.14	1.14	1.14	1.14	1.14	1.14		
None	R1 Pond	0.123	0.141	0.078	0.036	0.078	0.036		
50 %		0.062	0.071	0.039	0.018	0.039	0.018		
75 %		0.031	0.035	0.020	0.009	0.020	0.009		
90 %		0.012	0.014	0.008	0.005	0.008	0.004		
None	R1 Stream	2.12	1.65	0.738	0.228	0.738	0.228		
50 %		1.06	0.826	0.369	0.114	0.369	0.114		
75 %		0.529	0.413	0.185	0.079	0.185	0.057		
90 %		0.212	0.165	0.079	0.079	0.074	0.023		
None	R2 Stream	2.84	2.21	0.989	0.442	0.989	0.305		
50 %		1.42	1.11	0.495	0.442	0.495	0.153		
75 %		0.709	0.553	0.442	0.442	0.247	0.104		
90 %		0.442	0.442	0.442	0.442	0.200	0.104		
None	R3 Stream	2.98	2.33	1.04	0.706	1.04	0.321		
50 %		1.49	1.16	0.706	0.706	0.520	0.161		
75 %		0.746	0.706	0.706	0.706	0.308	0.158		

PECsw (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		
90 %		0.706	0.706	0.706	0.706	0.308	0.158		
None	R4 Stream	1.90	1.48	0.663	0.392	0.663	0.205		
50 %		0.950	0.742	0.392	0.392	0.331	0.102		
75 %		0.475	0.392	0.392	0.392	0.176	0.092		
90 %		0.392	0.392	0.392	0.392	0.176	0.092		

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

Table 9.2.5- 20: PECsw values for FLU-7-OH, following single application of FLU SC 500 to apples according to surface water Step 4 (modelling use apple - early – 0.075 kg a.s./ha)

PECsw (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	D3 Ditch	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
50 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
75 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
90 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
None	D4 Pond	0.042	0.042	0.042	0.042	0.042	0.042		
50 %		0.042	0.042	0.042	0.042	0.042	0.042		
75 %		0.042	0.042	0.042	0.042	0.042	0.042		
90 %		0.042	0.042	0.042	0.042	0.042	0.042		
None	D4 Stream	0.046	0.046	0.046	0.046	0.046	0.046		
50 %		0.046	0.046	0.046	0.046	0.046	0.046		
75 %		0.046	0.046	0.046	0.046	0.046	0.046		
90 %		0.046	0.046	0.046	0.046	0.046	0.046		
None	D5 Pond	0.044	0.044	0.044	0.044	0.044	0.044		
50 %		0.044	0.044	0.044	0.044	0.044	0.044		
75 %		0.044	0.044	0.044	0.044	0.044	0.044		
90 %		0.044	0.044	0.044	0.044	0.044	0.044		
None	D5 Stream	0.034	0.034	0.034	0.034	0.034	0.034		
50 %		0.034	0.034	0.034	0.034	0.034	0.034		
75 %		0.034	0.034	0.034	0.034	0.034	0.034		
90 %		0.034	0.034	0.034	0.034	0.034	0.034		
None	R1 Pond	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		

PECsw (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		
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	0.002	0.002	0.002	0.002	<0.001	<0.001		
50 %		0.002	0.002	0.002	0.002	<0.001	<0.001		
75 %		0.002	0.002	0.002	0.002	<0.001	<0.001		
90 %		0.002	0.002	0.002	0.002	<0.001	<0.001		
None	R2 Stream	0.009	0.009	0.009	0.009	0.004	0.002		
50 %		0.009	0.009	0.009	0.009	0.004	0.002		
75 %		0.009	0.009	0.009	0.009	0.004	0.002		
90 %		0.009	0.009	0.009	0.009	0.004	0.002		
None	R3 Stream	0.020	0.020	0.020	0.020	0.009	0.005		
50 %		0.020	0.020	0.020	0.020	0.009	0.005		
75 %		0.020	0.020	0.020	0.020	0.009	0.005		
90 %		0.020	0.020	0.020	0.020	0.009	0.005		
None	R4 Stream	0.009	0.009	0.009	0.009	0.004	0.002		
50 %		0.009	0.009	0.009	0.009	0.004	0.002		
75 %		0.009	0.009	0.009	0.009	0.004	0.002		
90 %		0.009	0.009	0.009	0.009	0.004	0.002		

Table 9.2.5- 21: PECsw values for FLU-7- OH, following single application of FLU SC 500 to apples according to surface water Step 4 (modelling use apple -- late -- 0.075 kg a.s./ha)

PECsw (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	D3 Ditch	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
50 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
75 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
90 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001		
None	D4 Pond	0.036	0.036	0.036	0.036	0.036	0.036		
50 %		0.036	0.036	0.036	0.036	0.036	0.036		
75 %		0.036	0.036	0.036	0.036	0.036	0.036		
90 %		0.036	0.036	0.036	0.036	0.036	0.036		

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	D4 Stream	0.039	0.039	0.039	0.039	0.039	0.039		
50 %		0.039	0.039	0.039	0.039	0.039	0.039		
75 %		0.039	0.039	0.039	0.039	0.039	0.039		
90 %		0.039	0.039	0.039	0.039	0.039	0.039		
None	D5 Pond	0.040	0.040	0.040	0.040	0.040	0.040		
50 %		0.040	0.040	0.040	0.040	0.040	0.040		
75 %		0.040	0.040	0.040	0.040	0.040	0.040		
90 %		0.040	0.040	0.040	0.040	0.040	0.040		
None	D5 Stream	0.061	0.061	0.061	0.061	0.061	0.061		
50 %		0.061	0.061	0.061	0.061	0.061	0.061		
75 %		0.061	0.061	0.061	0.061	0.061	0.061		
90 %		0.061	0.061	0.061	0.061	0.061	0.061		
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	0.008	0.008	0.008	0.008	0.004	0.002		
50 %		0.008	0.008	0.008	0.008	0.004	0.002		
75 %		0.008	0.008	0.008	0.008	0.004	0.002		
90 %		0.008	0.008	0.008	0.008	0.004	0.002		
None	R3 Stream	0.004	0.004	0.004	0.004	0.002	<0.001		
50 %		0.004	0.004	0.004	0.004	0.002	<0.001		
75 %		0.004	0.004	0.004	0.004	0.002	<0.001		
90 %		0.004	0.004	0.004	0.004	0.002	<0.001		
None	R4 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		

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.