

Document Title

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

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

Secording to the Guidance Document SANCO/10187/2013/8--on preparing dossiers for the approval of a characteristic state of the control of the con Date Document MCP

Section 95 Fate and behaviour in the environmen.

According to the Guidance Documents ANCO/1018/2018/for applicants on integrating dossiers for the approvals 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
It is suggested that applicate SANCO/10180/2013 Charter SANCO/10180/201	ants adopt a similar approach showing revision pter 4, 'How to revise an Assessment Report.'	as and version history as outlined in



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CP9 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 Councy Directive 91/414/FCC 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 50% (250+250 g/K), abbreviation FLU FFS, SC 50% (250+250), is a Suspension Concentrate (SC) formulation containing 250cg/L of Muopykam and 250 g trifloxystrobin. This formulation is registered throughout Europe under trade names such as Jana Sensation, Luna Sensation SC and Moon Sensation. FLD+TFS SC 500 (250+250) was not a representative formulation of Bayer AG for the Anne 1 inclusion of Fluor am under Council Directive 91/414/EEC.

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

Table 9.1- 1: Intended application pattern

Crop	Timing	Namber &	Application	Maximum (Maximum
	¸∅ of Oʻ	of grantions		-22-1	application rate,
	application	applications		(rangel /	individual treatment
*	(range)				(ranges)
		_			🏏 [kg a.s./ha]
	<u> </u>		Agrays	[Lprod./ha]	Fluopyram
	BBCH 33-73%	r 6.™ .™		0.20	0.050
Lettuce (soil-less wiltivation,			7.0	0.8	0.200
high-teen greenhouse))′ ∜U',	0.0	0.200

CP 9.1

Please refer to Document MCA, Section 7.1.2. For information on the rate

Laboratory studies

of Maboratory studies of Pase refer to Document MCA, Section 7.1.2.1.

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 70.2.2.2

CP 9.1.2 Mobility in the soil

For information on mobility studies please refer to Document MCA, Section 79.4.

CP 9.1.2.1 Laboratory studies

For information on laboratory studies please refer to Document MCA, Section 7.1.1.1.

CP 9.1.2.2 Lysimeter studies

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

CP 9.1.2.3 Field leading studies

For information on field leaching rudies 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 soft

Table 9.13-1: 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 forr. factor	1.0403	0.2874
Max. occurrence of soil [%] 100	5.8	14.8
DisT ₅₀ soil 6 1000*	85.52 1)	50.3 ²⁾

^{*} default

¹⁾ worst case lab, non-normalized

²⁾ worst coe DisT50, including default degradation and leaching



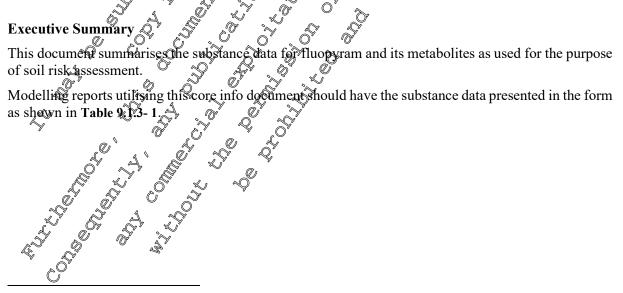
PEC_{soil} modelling approach

The predicted environmental concentrations in soil (PEC_{soil}) for the active substance fluopyram apoits 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 disploution of the compound in the upper 0-5 cm soil layer. A standard soil density of 1.5 g/cm³ was assumed. Copp 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 recommendations of the FOCUS groundwater guidance paper (FOCUS 2014a1).

Predicted environmental concentrations in soil (REC_{SOIL})

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

Data Point:	
Report Author:	
Report Year:	
Report Title:	Fluopyram (FLO): Core PECew, PECew, PECsoil FUR - Modelling core info
	document for groundwater, wirfacet after soil risk assessment of Europe
Report No:	EriSa-21-0077
Document No:	<u>₩</u> -7632©2-01-12
Guideline(s) followed in	none 1
study:	
Deviations from current	Current guideling not applicable
test guideline:	
Previous evaluation.	No, not previously submitted 5
GLP/Officially	No, not conducted under CLP/Officiall precognosed testing facilities
recognised tosting	
facilities:	
Acceptability/Reliability/	Yes V



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



	Tee are a visual
Data Point:	KCP 9.1.3/02
Report Author:	
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:	<u>M-763355-01-1</u>
Guideline(s) followed in	not applicable
study:	
Deviations from current	Current guideline: not applicable V
test guideline:	
Previous evaluation:	No, not previously submitted of the subm
GLP/Officially	No, not conducted under CLP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes A O Q O Q

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 fluoryram and its metabolites fluoryram-7-hydroxy (FLU-7-QH) and triffuoroactic acid (TFA) were calculated in a first tier approach using a Microsoft[®] facel spreadsheet. The use of fluoryram 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 DisT₅₀ of 1000 days (worst-case non-normalized trigger value (SFQ) for the parent compound fluopyram as worst case approach.

Table 9.1.3-2: Application pattern used for PEC a calculations of fluopyram

	Ŷ		App	lication		Amount
Individual Crop	FOCUS crop used for Intercontion	√ Seasom	Arterval	Plant Interception	BBCH Stage	reaching the soil per application
		ĺg Ģ r.s./ha∤Ç	[days]	[%]		[g a.s./ha]
Grapes	Vines	Ç 2 ≈Ş 0	7	2 × 60	53 - 73	2 × 20.0

Findings: The PECsoil 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}			Vi	nes	
(mg/kg)		Single ap	oplication	Multiple a	pplications
		Actual	TWA	Actua	TWA O
Initial		0.027	-	0.053	\$ - \$
Short term	24h	0.027	0.027	0.053	0.053
	2d	0.027	0\)027	0.053	9.053
	4d	0.027	© 0.027	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	9 .052 0	e 0.0%
	28d	0.026	0,026	A 0.05	0.053
	42d	00026	© 0.026		0.05
	50d	00.026	9026	\$ 0.05.1\$ £	© 0 2 0052
	100d	Q 0.025 Q	0.026	0.050	>0.051
Plateau concentratio	on (5 cm)	9.093		0.051	<u> </u>
DEC	S Q				
(PEC _{act} +PEC	soil plateau				-
Plateau concentration after PEC (PECact +PEC					



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

intervai					
	Vines				
	Single ap	pplication	Multurle a	pplications TWA	
	Actual	TWA	Actual	TWA	
	0.002	-	0003		
24h	0.002		© 0.003		
2d	0.002	(//)		0.003	
4d	0.002	(m) 0.002	0.003		
7d	0.002	0.002	0.002	0.003	
14d	0.001	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0003	~ U.U.U.	
21d	0.004	10° 0'801 %	0.003	0 0003	
28d	0,601	0.001C	0.902	0.003	
42d	6 .001	0.000	0.002	0.003	
50d	0.001	0.001	0.002	© 0.003	
100d	⊅ . ∜9 .001 °	\$ 0.00 V	9.001	0.002	
n (5 čml) er yzgar 1	\$\langle \sqrt{0.00}\$	\$ \	<0.001	-	
ccumulation soil plateral	0.002		0.003	-	
	2d 4d 7d 14d 21d 28d	Actual 0.002 24h 0.002 2d 0.002 4d 0.002 7d 0.002 14d 0.001 21d 0.004 28d 0.001	Single application Actual TWA 0.002 - 24h 0.002 - 2d 0.002 0.002 4d 0.002 0.002 7d 0.002 0.002 14d 0.001 0.002 21d 0.004 0.002 28d 0.001 0.0001	Single application Multiple at Actual TWA Actual 0.002 - 0.003 - 0.003 - 0.002 0.003 - 0.002 0.003 - 0.002 0.003 - 0.002 0.003 - 0.002 0.003 - 0.002 0.003 - 0.003 - 0.002 0.003 - 0.0	



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

•	ilitei vai				© ~
PEC _{soil}			Vi	nes	Ž,
(mg/kg)		Single a _l	pplication	Multiple applications Actual TWA	
		Actual	TWA	Actual	TWA
Initial		0.001	-	200 02	~ · · · · · · · · · · · · · · · · · · ·
Short term	24h	0.001	9 3 0 1	0.002	\$ \$\$\text{\$\ext{\$\text{\$\exiting{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exititt{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\texititt{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exitit{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exitit{\$\texititt{\$\text{\$\texitititt{\$\text{\$\text{\$\exitit{\$\text{\$\text{\$\text{\$\text{\$\text{\$\e
	2d	0.001	4 0.001	0.002	©0.002° ¢
	4d	0.001	0.001	0.002	\$\ 0.0\text{62}
Long term	7d	0.001	0.001	0.002	\$\int_{\infty} \(\text{\$0.002} \)
	14d	<0.001	0.004	002	0.002
	21d	<0.004	© < © .001	0.002	
	28d	<0.001	\$0.00£	0:901	Ø 0.002
	42d	€ 0.00 €	< 9.0001	0.001	0,002
	50d	<0.001	< 0.001	0.001	•
	100d@	<0.001		9 .001	0.001
Plateau concent		(< 0.0¢) (()	\	<0.00	-
	after 🎾 ar 1	0' 2 2	, ,		
(PEC _{act} +	PEC _{accumulation}	0.001		0.002	-

PECsoil for trifloxystrobin and its metabolites

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

CP 9.2 Pate and bedraviour in water and sediment

For information on aerobic minoralisation in surface water studies please refer to Document MCA, Section 72.2.2.

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

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 (PECgw) are presented below

Modelling parameters for <u>fluopyram</u> and its metabolites FLU-7-O **Table 9.2.4-1**:

Calculations of predicted	environmental concentrat	ions in groundwater (1 Le	gw) are presented believe.
Endpoints for PEC _{gw} Table 9.2.4- 1: Model	ling parameters for <u>fluopy</u>	ram aud its metabolites FL	.U-7-OH and TEX
Compound	Fluopyram	Juopyram-7-hydroxy	Trifluor@cetic and
		(FLU-7-QH)	(TFA)
Molecular mass (g/mol)	396.7	4,2.7	114
Water solubility (mg/L)	19 (20°C)	33.75 (2580)	\$500000 (20°C)
Saturated vapour pressure (Pa)	1.2 E-6 (20°C)	1,95 E-9,20°C) O	1.0 F (20 - 50°C) (000) (000) (000) (000)
DT ₅₀ in soil (d)	- N Y		
TDS f _{NE lab}	0.5 25 (TierQa)		
TDS $k_{des \ lab}$ (1/d)	0,0285 (Toper 2a) 232.1	7 % - 2 3	-
Koc (mL/g)		0 1009	<u></u>
Kom (mL/g)	34.70	58.1	0
Freundlich exponent	0.843	© 0.929 Q	1

The predicted environmental concentrations in groundwater (PEC) for the active substance fluopyram were calculated using the signulation models PEARL, PELMO, and MACRO (scenario Châteaudun) following the recommendations of the EOCUS working group on groundwater scenarios.

The simulations are carried out over 26 years for perticides which are applied every year. The simulation length increases to 46 and 66 years for pericides 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 ground water concentrations in the percolate at 1 m depth under a treated plantation were evaluated and were taken as the relevant PEC 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 Salculations were conducted based on mean soil half-lives, referenced to standard temperature and noisture conditions. Crop interception will reduce the amount of a compound reaching the soft and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the recommendations of FOCUS 2014a².

A sammaro 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 trifluor acetic acid (TFA) were considered for all use patterns in grapes.

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

Data Folit. Ref 7.2.4.170g () () () ()	
	7
Report Author:	
Report Title: Fluopyram (FLJ): Com PEC , PEC , PEC oil EUR - Modelling core in	nfo
document for ground water, starface water and soil risk assessment in Europe	е
Report No: En \$2-21-0077	
Document No: M-7632 \$\frac{10}{2} \text{0} \text{0} \q	
Guideline(s) followed in strone study:	
study:	
Deviations from current Current guideline: not applicable	
Previous evaluation No, not previously submitted O	
GLP/Officially No not conducted under LP/Officially recognised testing facilities recognised testing	
facilities: Yes	
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:

- FOŒYS PEARI
- FOCUS PELM©
- 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 Table 9.2.4.1-1 and Table 9.2.4.1-2.



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

Parameter	Unit	Fluopyram	Fluopyram-7- hydroxy	Trifluoroacetic acid
Common) (V) (S)
Molar mass	(g/mol)	396.7	412.7	114.0 / 228.0*
Solubility	(mg/L)	19	33.8	50 0000
at temp.	(°C)	20	25 🛴 "	20 %
Vapour pressure	(Pa)	1.20E-06 🐨	1.551 09	© 1.0 9 ⊕ 06 √ 1
at temp.	(°C)	20	, Qð	20 S
Freundlich	(-)	0.843	Qn 928 ° &	
exponent			~ 10.7200 Q	
fne, TDS	(-)	n.a. ¹⁾ /0.525 ²⁾ 3)		
kdes, TDS	(1/day)	n.a (7 0.0285 ^{2) 3)}		
Plant uptake factor	(-)	$0^{1}/0.3026^{2),3}$	$0.7256^{2),3)}$	
Walker exponent	(-)	20°7 27		0.7
PEARL parameters				
Substance code	(-)	FKU ¹⁾ / FICU21 ²⁾ FLU23 ³⁾	70H ³ /70H21 ²⁾ /\$	TFQ ⁷⁾ / TFA21 ²⁾ / TFA23 ³⁾
DT_{50}	(days)	298.1%) / 254\bg^) / \tilde{\mathbb{Q}}16.4\bg^{\mathbb{Q}}	5 17.5 F	1000
Formation fraction			0.63 42	© 0.5402
Molar activ. energy	(kJ/mol)	6 5.4	4© .4	يُّو 65.4
Kom	°Z(mL/g)	34.7	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Ç 0
PELMO parameters				9
Substance code		S S		B1
Rate constant	0 (1/day) «	$0.00272^{2} / 0.0032^{3}$	Ø.039 54	0.00069
Q10	(Q-) O	4 258 D	2,5,8	2.58
Koc 🗞	(mL/g)	2 32.1	★ 90.2	0
MACRQ				
parameters		© \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	△ ÅÖH¹) / 7OH21²) /	TT (1) (TT (2))
Substance code)	©FLU¹√√FLU242°// ∀ ØLU23³© %	7OH21 ²)/	TFA ¹⁾ / TFA21 ²⁾ / TFA23 ³⁾
Exponent moisture		0.40	0.49	0.49
Exponent			0.0948	0.0948
temperature	l 0° ≈∩″ <i>á</i>			
FRACEQ	(-)5 () (1/day)	$m_{\rm a}$ / $0.344^{(2)3}$	0	0
SORPR®TE	(1/day)	0.0098^{23}	0	0

¹⁾ Tiet 1

The model PELMO cannot deal with formation fractions > 1. Therefore, a formation fraction reflecting triftuoroacene acid (TFA) formation per CF3 moiety (related to max. ff 1) was used in combination with the molac mass of 2 TFA molecules. This adaptation of the formation in soil can be assumed reliable in case of FA, since it is a non-sorbing metabolite, where equilibrium sorption is of no concern.

²⁾ Tier 2a 1

³⁾ Tier 2a 2

^{*)} Pelmo: Molar mass of TNA multiplied by 2, in combination with overall formation fraction per CF3 moiety, 0.2701., i.e. 0.5 * formation traction per FLU molecule. This is done to adapt for limitations in PELMO with formation



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

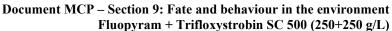
	Tier 1	Tier 2a 1	Tier 2a 2
Degradation fraction	FLU → 7OH: 0.6342	FLU21 → 7OH21: 0.6342	FLU23 → 7OH23: 0.8342 4
from \rightarrow to	$FLU \rightarrow TFA: 0.5402$	$FLU21 \rightarrow TFA21: 0.5402$	$FI@23 \rightarrow TFA2370.5402$
(-) (FOCUS PEARL)			
Degradation rate	Active Substance \rightarrow A1:		Active Substance → Al:
from \rightarrow to	0.0014748	0.0017280	0.0020306
(1/day) (FOCUS PELMO)	Active Substance \rightarrow B1:	Active Substance → B	Active Substance B1
a), b)	6.28E-04	7.36Ê¥04	8.65E-9# 🙄 🗸
	Active Substance →	Active Substance	Active Substance → \$\(\)
	BR/CO2: 2.23E-04	ER /CO2: 2.61E 0 /4	BR €02: 3.06E-0€
	$A1 \rightarrow BR/CO2: 0.0395406$	$A1 \rightarrow BR/CO2: 0.0399406$	
	B1 → BR/CO2: 6.93E-049	$B1 \rightarrow BR/GO2: 6.93E-04$	BÍ → BŘ/CO2; 6.93Æ-04
Conversion factor	FLU → 7OH:	FJO21 7 OH21 V	FLU 2 3 → 7ÔH23:
from \rightarrow to	0.659777737	0.6597 <i>1</i> 07	0.6997777
(-) (FOCUS MACRO) c)	$7OH \rightarrow TFA:$	FLU2y→ TFA21: 4	EŁU23 → TFAS:
·	0.155257118	0.155/25710	0.155 25 71

Data Point:	KCP 9.2-4.1/03 \$\tilde{\text{\$\tilde{\tilde{\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\text{\$\tilde{\tilde{\tilde{\tilde{\tilde{\text{\$\tilde{\text{\$\tilde{\tiilie}\tiii}}}\tilde{\tilde{\tilde{\tilde{\tilde{\tilde{\ti
Report Author:	2022 PEARL, PELMO, MACRO EUR (Tor 1) See in apples, spring coeals, winter cereals and vines in Europe
Report Year:	
Report Title:	Fluopyrand (FLU) and metabolitics: PECgw FOCTS PEARL, PELMO, MACRO
	EUR (Toor 1) Ose in apples, spring coreals, winter cereals and vines in Europe
Report No: Document No:	PÉnSa-M-0026 N N N N
Document No:	M-763352 Q1-1
Guideline(s) forowed in	porte V & S S
study:	
Deviations from current	Current guid@ine: not applicable
test guideline:	
Previous evaluation:	No, not previous submitted & S
GLP/Officially	No, not conducted under GLP/Officially recognised testing facilities
recognised testorg	
tacilities:	
Acceptability/Reliability:	Yes y y y
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Š _O ^v	Floopyraid (FLU) and metabolites PECgW FOCUS PEARL, PELMO, MACRO EUR (The 1) Ose in apples, spring careals, winter cereals and vines in Europe EnSa-21-0026 M-763352-01-1 porte Current guid@ine: not applicable No, not previously submitted Yes Yes

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



Data Dainte	VCD 0 2 4 1/04
Data Point:	KCP 9.2.4.1/04
Report Author:	2021
Report Year:	
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACKO
	EUR (Tier 2a 1, appl. every year) - Use in apples, spring coe als, winter coe als
D. AM	and vines in Europe
Report No:	EnSa-21-0053
Document No:	M-763421-01-1
Guideline(s) followed in	none S S S S
study: Deviations from current	
	Current guideline: not applicable
test guideline: Previous evaluation:	No. not previously submitted
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facilities:	
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Report Author:	
Report Year:	2021
Report Title:	
Report Title:	Fluoryram (ELU) and metabolites: PECgw ROCUS PEARO, 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-763428-60-1 O S S S S S S S S S S S S S S S S S S
Guideline(s) followed	none
study:	
Deviations from corrent	Current guideline: not applicable
test guideline:	Current guidenne. Advappheaoic
	No, not previously submitted \(\text{Q} \)
Previous evaluation:	No. not previously submyseed to
GLP/Officially	No not conducted under GLP/Officially recognised testing facilities
facilities:	
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recognised testing facilities: Acceptability/Reliability:	





Data Point:	KCP 9.2.4.1/06
Report Author:	2021
Report Year:	2021 Elway ware (ELLI) and matchalitas DECary EOCUS DEADL DELMO MACO
Report Title:	Fluopyram (FLU) and metabolites: PECgw FOCUS PEARL, PELMO, MACK
	EUR (Tier 2a 1, appl. every 3rd year) - Use in apples, spring cereals, winter
D	cereals and vines in Europe
Report No:	EnSa-21-0055
Document No:	M-763423-01-1
Guideline(s) followed in	none S
study:	<u> </u>
Deviations from current	Current guideline: not applicable
test guideline:	
Previous evaluation:	No, not previously submitted
GLP/Officially	No, not conducted under GLP officially recognised testing facilities >
recognised testing	To, not conducted unity of the state of the
facilities:	
Acceptability/Reliability:	Yes XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
11000 11100	
Data Point:	KCP 9.2.4 Q 07
Report Author:	
Report Year:	2021
Report Title:	Fluoryram (FLU) and metaliolites: PECgy FOCUS PEARD, PELMO, MACR
1	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-769424-60-1
Guideline(s) followed	none A A
study:	
Deviations from corrent	Current guideline: not applicable
test guideline:	Current guidenne, novappriegore
	No, not previously submitted & W
Previous evaluation:	A A A A A A A A A A A A A A A A A A A
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GLP/Officially recognised testing	No not conducted under GLP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes @
facilities: Acceptability/Reliability:	
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Data Point:	KCP 9.2.4.1/08
Report Author:	0
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:	<u>M-763425-01-1</u>
Guideline(s) followed in	none & & & & & & & & & & & & & & & & & & &
study:	
Deviations from current	Current guideline: not applicable
test guideline:	
Previous evaluation:	No, not previously submitted
GLP/Officially	No, not conducted under GLPW fficially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes V V V V V
Data Point:	KCP 9.2.4 Q09 2 2 2 2 2 2
Report Author:	
Report Year:	2021
Report Title:	Fluoryram (FLU) and metabolites: PECgw FOCUS PEARD, PELMO, MACRO
	EUR (Tier 2a 3, appl. every 3rd year) - Use in apples, spring cereals, winter
	cereals od vines in Europe
Report No:	EnSa-21-00669
Document No:	M-769426-01 0 0 0 0
Guideline(s) followed	none & O &
study:	
Deviations from corrent	Current guideline: not applicable S
test guideline:	
Previous evaluation:	No, not previously submated
b	

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

conducted under GLP/Officially recognised testing facilities

Methods and Materials

Acceptability/Reliability

GLP/Officially recognised testing

facilities:

Predicted environmental concentrations of the active substance fluopyram and its major soil degradation products in goundwater recharge (PEC_{sp}) were calculated for the use in Europe, using the simulation models 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 PECgw calculations of fluopyram

Individual	FOCUS	Rate	Interval®	Plant interception	BBCH stage	Amount reaching sou
crop	crop	(g a.s./ha)	(days)	(%)((-)	Qg a.s
Vines I	Vines	2 × 50	67	2 × 60	7° 53© 73 6	2 × 20.000
Vines II	Vines	2 × 50 &	7, .	2 × 75	√ 5 3 - 7 3	\$2× 12,590

Input parameters – tiered approach:

A detailed description of the parameter used at the different steps is presented in Table 92.4.1-0. 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 metabolities used for modelling

	Tier 1	Ther 2a 1	A Pier	2a 2
	DT ₅₀ TSCF		Date o	TSCF
FLU	298 (1 a) (2 gy)	25(4.4 b) 0.9026 f)	216.48°)	0.3026 f)
FLU-7-OH	25 d) & 00 e) S	77.5 d) 00.7256 f) 00.7256 f)	77.5 d)	0.7256 f)
TFA	6 1000 × 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1000° 5 0.10° 5	(F) 1000 e)	0.17 ^{g)}

- a) DegT50 field matrix
- b) TDS, DT50 la Pequilibrum
- c) TDS, DT5@jeld 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 Deg T₅₀ matrix value of 298.1 d derived from field dissipation studies was used for fluopyran.

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, aboratory 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 0.72560 (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 Ta 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 (2010b). Crop interception was taken into

For use patterns with large application time windows, multiply starting times for modelling were shosen 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 > 00 d, a furthe application date was set to





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 2rd year Every 2rd year Every 2rd year Every 3rd year Ever	Hamburg (144) (226) (144) (226) (3 Jun (154) (212) (154) (212) (164) (212) (164) (212) (164) (212)	Hamburg 03 un 31 Jul (212) Jokioinen 03 Jun (212) Kaemsmuenster 03 Jun (212) Okehampion 0	Hamburg 03 Jun 31 Jul (212) Jokiointen 31 Jul (212) Kremsmuenster 03 Jun (124) (212) Okehampton	Individual cro	op Vines	s I V	ines II
Hamburg (22th) 103 Jun (154) Jokioinen Keemsmuenster (144) Okehampton (154) Okehampton (154)	Hamburg (22th) 103 Jun (154) Jokioinen Keemsmuenster (144) Okehampton (154) Okehampton (154)	Hamburg (22th) 103 Jun (154) Jokioinen Keemsmuenster (144) Okehampton (154) Okehampton (154)	Hamburg (22th) 103 Jun (154) Jokioinen Keemsmuenster (144) Okehampton (154) Okehampton (154)	Repeat interval	l for Every y	year Eve	ery year
Hamburg (226) Hamburg (31 Jul) Jokioinen (212) Kæmsmuenster (32 Jul) Kæmsmuenster (32 Jul) Okehampton (212)	Hamburg (226) Hamburg (31 Jul) Jokioinen (212) Kæmsmuenster (32 Jul) Kæmsmuenster (32 Jul) Okehampton (212)	Hamburg (226) Hamburg (31 Jul) Jokioinen (212) Kæmsmuenster (32 Jul) Kæmsmuenster (32 Jul) Okehampton (212)	Hamburg (226) Hamburg (31 Jul) Jokioinen (212) Kæmsmuenster (32 Jul) Kæmsmuenster (32 Jul) Okehampton (212)	app. events	Every 2 ^{no}	d year Ever	y 2 nd year
Hamburg (144) (226) Hamburg (154) (218) Jokioinen (154) (218) Kaemsmuenster (154) (212) Okehampion (154) (212)	Hamburg (144) (226) Hamburg (154) (218) Jokioinen (154) (218) Kaemsmuenster (154) (212) Okehampion (154) (212)	Hamburg (144) (226) Hamburg (154) (218) Jokioinen (154) (218) Kaemsmuenster (154) (212) Okehampion (154) (212)	Hamburg (144) (226) Hamburg (154) (218) Jokioinen (154) (218) Kaemsmuenster (154) (212) Okehampion (154) (212)		Every 3 rd	year Ever	y 3 rd ywar
Hamburg 00 Jun 31 Jul (212) Jokioinen	Application technique	Spra	y 🐺 S	Spra			
Hamburg (226) Hamburg (31 Jul) Jokioinen (212) Kremsmuenster (32 Jul) Okehampton (164) Okehampton (212)	Hamburg (226) Hamburg (31 Jul) Jokioinen (212) Kremsmuenster (32 Jul) Okehampton (164) Okehampton (212)	Hamburg (226) Hamburg (31 Jul) Jokioinen (212) Kremsmuenster (32 Jul) Okehampton (164) Okehampton (212)	Hamburg (226) Hamburg (31 Jul) Jokioinen (212) Kremsmuenster (32 Jul) Okehampton (164) Okehampton (212)	Absolute / Rela	ative Absorb	Ste Al	Seolute
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Okehampion O Jun (212)	Chateaudun	20°M	ax Q Q1	4 Aug (226)			
Okehampton S - S - S - S - S - S - S - S - S - S	Okehampton S - S - S - S - S - S - S - S - S - S	Okehampton S - S - S - S - S - S - S - S - S - S	Okehampton S - S - S - S - S - S - S - S - S - S	Hamburg	03Ju		9- 81 Jul (212)
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Okehampton Piacenza Porte 14 May (226) 14 Aug (221) Sevilla 04 May 10 Jul (191) - Thiva 17 Jul (198)	Okehampton Piacenza 24 May (144) Porto 14 May (220) - 14 May (221) - Sevilla 04 May 10 Jul (191) - Thiva 17 Jul (124) (128) - 17 Jul (198) - - - - - - - - - - - - -	Okehampton Piacenza Portec 14 May (144) (226) 10 Jul (191) Thrva 01 May 17 Jul (198) - - - - - - - - - - - - -	Okehampton Piacenza 24 May (144) Porte 14 May (226) - 04 May 10 Jul (191) - Thiva 17 Jul (198) - - - - - - - - - - - - -	Kemsmuenste	03 J		31 Jul (212)
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Sevilla	Sevilla	Sevilla	Sevilla	Porto	14 ₀ M ₂	ay S	9 Aug (221)
Three 17 Jul (198)	17 Jul (129) (198) -	Three 17 Jul (128) (198) -	Torva 17 Jul (198)	Sevilla (F	0 04 M	Ay 3'	- 10 Jul
				Tova A	0 0 - 01 Mi	10° 1	



Findings:

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

Tier 1: DT₅₀ soil for fluopyram based on field data

ralues for fluopyram and its metabolites are given in the following tables.

For fluopyram based on field data

Tier 1 PEC_{gw} for fluopyram and its metabolites on Vinex I (with FOCUS PEAR)

PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 60% interception, 7 d app interval.

80th percentile PEC_{gw} at 1 m soil depth (μgQ) **Table 9.2.4.1-6:**

		80 th percentile PEC _{gg} at 1 m soil depth (μgΦ) Fluopyram Fluopyram -7- TriDuoroasetic acid hydroxy						
Crop	Scenario	Fluor	yram	Æluopy	rajn-7- 🎗	TriDuoro	setic acid	
333 F	15 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<u>«</u>		o hyd	røxy 🍼			
		PEARL	PELMO	PEART	PELMO	PEARL	PELMO °	
Vines I	Chateaudun	0,699	0.675	6 098 (0.093	£2.689	2.604	
	Hamburg	0.606%	0:679	~0.092°	9 701	D 1.990	Q.683	
	Kremsmuenster	0.460	70.576 ²	0.065	∂ [®] 0.082 [©]	1\$45 <u>«</u>) 1.647	
	Piacenza	\$554 ®	0.59	9 0.078 L	02085	3.034	1.675	
	Porto S	0.284	0.358	0.050	Ø0.068	1.103	1.206	
	Sevilla 👸 💍	0.38 2	0.130		0.028	\$2.522	5.657	
	Thiva	0.422		6 0.0 5 9	ð.d.57 E	5.922	6.496	
		J' @MA(CBO 5	(7)	ORO &	MAG	CRO	
قُ ا	Châteaudun	, 0.2	258		040~\$	3.1	94	

Table 9.2.4.1. 7: Ther 1 PEC gw for fluopyram and its operabolites on Vines II (with FOCUS PEARL/PEL MO/ MACRO) 2 × 50 g a.s./ha, 2 × 5% interception, 7 d app. interval

		80 th percentile REC _{gw} at 1 m soil depth (μg/L)						
Crop	Scenació (FLOOP	yrane (Fluopyram-7- hydroxy		Trifluoro	acetic acid	
Vines II	Chateaudun Hambriso	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	
Vines II	Chateaudun	0.365 Q321	331	0.055	0.050	1.695	1.652	
7/	1141119889	Q321 ~	0.341	0.051	0.056	1.244	1.676	
	Kremsmuenster	© 0.235	0.289	0.037	0.046	0.916	1.031	
	Ridcenza	0328	0.336	0.048	0.053	1.949	1.048	
	Porte 5	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 Y	0.204	0.149	0.031	0.026	3.702	4.065	
		MAC	CRO	MACRO		MACRO		
	Châteaudun	0.0	90	0.0)16	1.4	135	



Tier 2a 1: DT₅₀ soil for fluopyram (TDS) based on laboratory data

Annual application

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% intercention 7 Pearling application **Table 9.2.4.1-8:** application

	80th percentile PECgw at 1 m soil depth (Hg)L)						
Crop	Scenario	Fluop	oyram 🔻	Fluopy hyd	ram-7- Joxy	Trifluoro	etic acid
		PEARL	PALMO	PEARL	F ELMQ	PEARL	PELMO
Vines I	Chateaudun	0.290 &	0.224°	3 9.050 ⊀	0.042	©2.681°×	2:476
	Hamburg	0.283	0.2 50	0.05	3 .052	1.957	\$2.512€°
	Kremsmuenster	0,203	~0.22.(~	0.039	Å 0.045 F	J.457	1.50
	Piacenza	Ø.257	0.296	\$\sqrt{0.044}^3	% 057	2.99	⊕622
	Porto	0.125	≈Ø.157 ×	0:034	2 0.0415	1994	\$\tilde{Q}\$ 1.123
	Sevilla	© 31 0	0.016	(5)030 C	0.006	2.434	5.142
	Thiva	°>0.139,	0.960	0.026	©0.015	5.792	5.880
		S MAI	RO TO	MAN	RO	S MAG	CRO
	Châteaudup	\$ 6 .0	003	0.0	003	3.1	24

for Anopyram and is metabolites on Vides II (with FOCUS PEARL/ MO/ MXCRQ) – 2 × 50 g a.s./ha, 2 × 5% interception, 7 d app. interval, annual fication

		80 th percentile PEC at 1 m soil depth (μg/L)					
Crop	Scenario 5	Fluop	yram (Fluopy hydi		Trifluoroacetic ac	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chatea dun	1 31	0.08	0.026	0.020	1.688	1.558
	Hamburg	$\mathbb{C}_{0.135}$	20 108	0.028	0.026	1.231	1.568
*	Fremsmilenster	0.033	0.102	0.020	0.022	0.921	0.999
, y	Piacenza C	0.143	0.158	0.026	0.033	1.911	1.006
	Parto S	0.143	0.078	0.019	0.023	0.704	0.712
	Seville &	√ 054	0.004	0.013	0.002	1.524	3.216
	Thiva	0.060	0.015	0.012	0.005	3.634	3.666
		MAC	CRO	MAC	CRO	MAG	CRO
	Châteaudun	<0.	001	<0.	001	1.4	17



Biennial application

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

			80 th percen	tile PEC _{gw} a	nt 1 m sourd	lepth (µg/L)	
Crop	Scenario	Fluor	oyram 🔻		rani-7-	Trifluoro	acetic acid
		PEARL	PELATO	PEARL	PELMO	PEAR	PEOMO
Vines I	Chateaudun	0.103	10 .080	0.021	© 0.017 Q	1 Ø 15	1.388
	Hamburg	0.117 🐇	\$// ~//	20026 ×	y 0.026	©0.963×	1:049
	Kremsmuenster	0.073	0.083	0.016	% 019	0.721	♣ 9.849ॣ ∘
	Piacenza	0.488	°>0.106	0.018	\$\ 0.023\ [©]	1.532	0.903
	Porto	Ø.045	0.0 % 5	0.014	0 018	0.52	6 547
	Sevilla	0.04	°√0.005 √	0.09	3 0.0035	1860	2.648
	Thiva	0 3042	0.019	0,009	0,00%	©2.308°\$	3.291
		MA	CRO	SMA (CRO C) OMA(CRO
	Châteatidun O	0.0	GY (, Q5	NO 3	J 1.5	587

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

			80th percen	tile PECgw a	№ 1 m soil d	epth (μg/L)	
CKO p	Scenario	Fluop	yram,	Fluopy	ram-7- roxy	Trifluoroacetic acid	
	Clareaudair	PFARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Cloreaudan .	0.048	©.034 ©	0.011	0.008	0.772	0.875
.4	Hambing ~	£Q055	0.0 5	0.014	0.013	0.591	0.661
	Kremsmuenster	$\mathbb{Q}_{0.03}$	92,038	0.008	0.010	0.458	0.531
4	Piacenza	0.649	$\sqrt[8]{0.057}$	0.011	0.013	0.977	0.576
	D 4 ///2 & 4	0.022	0.026	0.008	0.010	0.333	0.345
	Sevilla	7 0.0 f	0.002	0.005	0.001	0.853	1.693
	Thiva 🛴	6 016	0.006	0.004	0.002	1.457	2.020
	Thiva S	MAC	CRO	MAG	CRO	MAG	CRO
	Phâteaudun	<0.	001	<0.	001	0.7	739



Triennial application

Table 9.2.4.1- 12: Tier 2a 1 PEC $_{gw}$ for fluopyram and its metabolites on Vines I (with FOCUS PEAR2)/PELMO/ MACRO) – 2 × 50 g a.s./ha, 2 × 60% interception, 7 d app. interval, triennial application

		80 th percentile PEC _{gw} at 1 m soll depth (μg/L)					
Crop	Scenario	Fluop	oyram		ram 7-	Trifluoro	acetic acid
		PEARL	PEL	PEARL	PELMO	EAR P	PROMO
Vines I	Chateaudun	0.055	0 .042	0.013	© 0.010 Q	0842	0.992
	Hamburg	0.061 🐇	0.0 5 7°	20 014 ≪	PQ.0	©0.621°×	0.771
	Kremsmuenster	0.042	0.0 46	0.010	% 011	0.495	♣ 9.590 <u></u> °
	Piacenza	0.048	°>0.059	0.011	1, 0.01 4	0.932	0.554
	Porto	Ø.023	0.098	\$0.00g	0 (0)10	0.336	6355
	Sevilla	0.020	°√0.002 √	0.006	©0.0015	0.587	\$\tilde{Q}\$ 1.579
	Thiva	\$ \$020	0.000	0,005	0.003	رِيرُّةً.611 كُلِّ	2.160
	J,	MA	CRO	SMA(CRO) OMA(CRO
	Châteardun O		G Ø1	, \$0	Ø01 🔊	J 1.0)18

Table 9.2.4.1- 13: The 2a 1 PEC of the fluor pyram and its inetabolites on vines U (with FOCUS PEARL/PELMO/MACO) - × 50 g a.s./ha 2 × 75% interception, 7 d app. interval, triential application

			80th percent	tile PEC _{gw} a	 W1 m soil d	epth (μg/L)	
(Stop)	Scenario .	~	yram, ~	Flûspy	ram-7- roxy	Trifluoroacetic acid	
	Clareauden	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Cloreaudan	0.025	©.018 ©	0.006	0.005	0.531	0.624
4	Hambing ,	£ Q)29	0.0 2	0.008	0.008	0.390	0.445
	Kremsmuenster	©0.012	92,020	0.005	0.006	0.306	0.358
	Pracenza 0	0.625	0.030	0.006	0.008	0.602	0.353
~	Porto	0.011	0.013	0.004	0.005	0.213	0.224
	Savila) 0.00°	0.001	0.003	< 0.001	0.497	0.973
	Thiva 🛴	₽ 007	0.003	0.002	0.001	0.976	1.362
	Thiva S	MAC	CRO	MAG	CRO	MAG	CRO
	Châteandun	<0.	001	<0.	001	0.5	512



Tier 2a 2: DT₅₀ soil for fluopyram (TDS) based on field data

Annual application

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% intercention 7 per section 2 p Table 9.2.4.1- 14: application

			80 th percen	tile PEC _{gw} a	nt 1 m soil d	lepth (µg/L)	
Crop	Scenario	Fluop	Fluopyram		rim-7- oxy	Trifluoro	Retic acid
		PEARL	PALMO	PEARL	F ELMQ	PEARL	PELMO
Vines I	Chateaudun	0.147 🐒	0.1 03 °	3 0.035 ⊀	~ ~	2 .724~	2%521
	Hamburg	0.157	QU 35	0.040	3 .038	2.063	\$2.613€°
	Kremsmuenster	0,109	* 0.120	0.029	\$\tag{0.033}\$	J.476	1.623
	Piacenza	Ø.142	0.1%	0.033	0 46	3.01	⊕652
	Porto	0.066	≈ 0 .082 €	0:024	2 0.0305	1.098	2 1.151
	Sevilla	© 057	0.00	6 5019	0.003	2.473	5.216
	Thiva	°>0.057,	0.020	© 0.016	©0.008	5.808	5.965
		O MAI	RO TO	MAN	RO	MAC	CRO
	Châteaudun	\$ 3	.001	0.0	001	3.1	50

Tier 2a 2 PE (for thropy am and its metabolites on Vites II (with FOCUS PEARL/PEL MO/ MACRO) – 2 × 50 g a.s. (ha, 2 × 75% interception, 7 d app. interval, annual application

EG		80 th percentile PEC at 1 m soil depth (μg/L)					
Crop	Scenario 5	Fluop		Fluopyram-7- hydroxy		Trifluoroacetic acid	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Chateandun	19 063	0.038	0.017	0.013	1.710	1.585
	Harmburg Q	$\mathbb{C}_{0.07}$	10,056	0.021	0.019	1.249	1.630
***	Fremsminenster	0.00Å7	0.053	0.014	0.016	0.932	1.017
~ Y	. 🙉' ''	0.078	0.092	0.019	0.027	1.925	1.021
	Parto V	0.078	0.039	0.013	0.016	0.708	0.730
	Seville &	√ 0021	0.001	0.008	0.001	1.544	3.260
	Thiva	0.023	0.004	0.007	0.003	3.644	3.718
		MAC	CRO	MAC	CRO	MAG	CRO
	Châteaudun	0.0	15	0.0	005	1.4	105



Biennial application

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

			80 th percen	tile PEC _{gw} a	nt 1 m soard	lepth (µg/L)	
Crop	Scenario	Fluor	oyram 🔻		ram 7-	Trifluoro	acetic acid
		PEARL	PELOTO	PEARL	PELMO	PEAR P	PFO MO
Vines I	Chateaudun	0.048	© .034	0.014	© 0.011 Q	1027	1.39
	Hamburg	0.060 🐇	0.055°	3 .019 ×	QQ.0	©0.982×	1:087
	Kremsmuenster	0.036	0 040	0.010	% 013	0.745	♣ 9.865 <u>~</u> °
	Piacenza	0.043	~0.058~	0.013	\$ 0.01 6	1.540	0.946
	Porto	Ø.020	0,0 %	\$0.00g	0013	0.52	6 3557
	Sevilla	0.016	≈0 .001 €	0.006	\$0.00 ₁ \$	1.872	2.700
	Thiva	0 5015	0.000	005	0.003	(2.317°)	3.344
	Z,	MA	CRO) MA	CRO
	Châteardun O	<i>√</i> <0,	6 61		Ø01 🔊	J 1.5	581

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

			80th percen	tile PEC _{gw} a	№ 1 m soil d	epth (μg/L)	
ÇK o p	Scenario	Fluopyram Fluopyram-7-			ram-7- roxy	Trifluoroacetic acid	
	Clareaudain	PFARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Cloreauden .	0.02	©.013 ©	0.007	0.005	0.780	0.881
.4	Hambing ~	£Q) 27	0.02	0.010	0.009	0.609	0.685
	Kreinsmuenster	©0.015	9017	0.006	0.007	0.461	0.538
4	Piacenza		\gg 0.030	0.007	0.010	0.983	0.583
, A	D ()	0.009	0.012	0.005	0.007	0.336	0.352
	Sevilla) 0.00°C	0.001	0.003	< 0.001	0.858	1.725
	Thiva 🛴	≈0 005	0.002	0.002	0.001	1.463	2.051
	Thiva S	MAC	CRO	MAG	CRO	MAG	CRO
	Châteandun	<0.	001	<0.	001	0.7	738



Triennial application

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

			80 th percen	tile PEC _{gw} a	nt 1 m sou d	lepth (µg/L)	
Crop	Scenario	Fluop	oyram 🔻		ram 7-	Trifluoro	acetic acid
		PEARL	PEL	PEARL	PELMO	PEAR Q	PEO MO
Vines I	Chateaudun	0.024	0 .017	0,008	© 0.006 Q	0849	1.002
	Hamburg	0.030 🐇	0.0 2 7°	20 010 ×	V 0.Q.W	©0.627~	0.223
	Kremsmuenster	0.019	QQ22	0.000	% 008	0.499	♣ 9.595ू ∘
	Piacenza	0.024	°>0.03.1	0,007	1, 0.01 6	0.931	0.554
	Porto	Ø.009	0.092	0.005		0.33	6359
	Sevilla	0.00	≈ 0.001 €	0.003	3 0.0015	0890	\$\tilde{Q}\$ 1.571
	Thiva	0 5007	0.000	003	0,001	©1.623 °♥	2.187
		MA	CRO	SMA (CRO) OMA(CRO
	Châtea dun	<i>√</i> <0,	G 01		Ø01 🔊	J 1.0)20

Table 9.2.4.1- 19: Tier 2a 2 PEC_B 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

			80th percent	tile PEC _{gw} a	₩1 m soil d	epth (μg/L)	
(Kop	Scenario .	™	yram, ~	Flûspy	ram-7- roxy	Trifluoroa	acetic acid
	Clareaudain	PFARL	PELMO	PEARL	PELMO	PEARL	PELMO
Vines II	Cloreaudan .	0.00	. 0 .007 0	0.004	0.003	0.534	0.630
4	Hambing ~	£ Q014	Q 0.01Q	0.005	0.005	0.394	0.452
	Kreinsmuenster	0.00	2009	0.003	0.004	0.307	0.362
	Pracenza 0	0.001/2	0 .015	0.004	0.006	0.602	0.356
~	Porto	0.004	0.006	0.003	0.004	0.214	0.226
	Sevilla	× 0.06	< 0.001	0.001	< 0.001	0.498	0.973
	Thiva 🛴	≈ 0002	0.001	0.001	0.001	0.977	1.382
	4 4	MAC	CRO	MAG	CRO	MAG	CRO
	Châtean dun	<0.	001	<0.	001	0.5	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 fluopyrim and its metabolities for FOCUS PEARL/ PELMO/ MACRO calculations for all use patterns in gapes 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: DT₅₀ soil for fluopyram based on field data

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

Use pattern	Fluopyram Fluopyram-7 Trifluores cetic acid
Vines I, 2×50 g a.s./ha	0.09 0.09 0 5.922
Vines II, 2×50 g a.s./ha	0.365 0.055 5 5 3.062

Table 9.2.4.1- 21: Maximum FOCUS PEL FO PEC gw results of Luopycan and its metabolites in μg/L for the uses assessed — Tier 1 ②

Use pattern	Ž		, Ø	Juopyram C	Kluopyram-7- O O hydroxy	Trifluoroacetic acid
Vines I, 2×50 g a.s.				0.679	Ø .0.101 @	6.496
Vines II, 2×50 g acs.	/ha 🍆	4 4		√0.34x ×	0.056	4.065

Table 9.2.4.1-22: Maximum FOČUS MACRO PEC_{cw} 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	&.s./ha⊳ [©]		0.298	0.040	3.194
Vines II, 2×50	, .	8 8	Q (0.016	1.435

Tier 2a 1: DT50 soil for fluopyram (TDS) based on laboratory data

Annual application

Table 9.2.49-23: Maximum FOCUS PEARL PECgw results of fluopyram and its metabolites in μg/L for the uses as ossed – Tier 2a 1, annual application

Use pattern O S	Fluopyram	Fluopyram-7- hydroxy	Trifluoroacetic acid
Vines 150 g a.s./ha	0.290	0.054	5.792
Vines II, 2×50 g a.s./ha	0.143	0.028	3.634



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

Use pattern	Fluopyram	Fluopyram-7- hydroxy	Trifluoroacetic
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

Maximum FOCUS MACRO PECgw results of fluopycam and its morabolites in µg/I Table 9.2.4.1- 25: for the uses assessed – Tier 2a 1, annual application

Use pattern	Fluopypam	hydrovy	Triffuoroacetic agus
Vines I, 2×50 g a.s./ha	Ø.003 Ø ≥	0.003	3.124
Vines II, 2×50 g a.s./ha		Q <0.091	O 1.407

Biennial application

Maximum FOCUS PEARL PEC_{2w} results of Theopyram and its metabolites in μg/L for Table 9.2.4.1- 26: the uses assessed — Tier 2a 1, Diennia application

Use pattern	Fluopyr	am 🗸	Kuopyram-7-	Tri O uoroacetic acid
		0	hydróxy 🦃	, Q
Vines I, 2×50 g a.s./ha	Ø _ . 117		9.026	2.308
Vines II, 2×50 g a.s./ha &	0.050		0.014	1.457

Maximum FOCUS PELMO PEC results of fluopyram and its metabolites in µg/L for the uses assessed - Tier 2a 1, biennial application

Use pattern	Fliop	yram		Trifluoroacetic acid
Vines I, 2×50 g a.s./ha	\$\ \@\\ 0.1	6 9' , "\"	0.026	3.291
Vines II, 2×50 g a.s. Tha		57	0.013	2.020

Table 9.2.4.1₋ Maximum/FOCLS MACRO RECgw results of fluopyram and its metabolites in μg/L for the uses assessed Tier 2201, biguila application

Use pattern		Fluopyram	Fluopyram-7- hydroxy	Trifluoroacetic acid
Vines I, 2×50 g		9 .001	0.001	1.587
Vines II, 2×50	g@ks./ha	<0.001	< 0.001	0.739
	g w.s./na			



Triennial application

Table 9.2.4.1- 29: Maximum FOCUS PEARL PECgw results of fluopyram and its metabolites in μg/IØfor 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	, O.6116
Vines II, 2×50 g a.s./ha	0.029	0.008	\$\int 0.976\int 5

Table 9.2.4.1-30: Maximum FOCUS PELMO PEC results of fluoryram and its metabolites in Fg/L for the uses assessed – Tier 2a 1, priennial application &

Use pattern	Fluopyram Orifluoroacetic	acid
Vines I, 2×50 g a.s./ha	0.05	WY .
Vines II, 2×50 g a.s./ha	0.030 7 0.008 1.362	Ş

Maximum FOCUS MACRO PECgw results of fluopyram and its metabolites in μg/L Table 9.2.4.1- 31: for the uses assessed Tier 201, triennial application

Use pattern		Fluopyram	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	Raopyram-7-		Tri Q uoroacetic acid
Vines I, 2×50 g a.s./ha		3 0.001		0.001	2	1.018
Vines II, 2×50 g a.s./ha		0<0.00r	***	<0.001		0.512

Annual application

Maximum COCUS PEARL PEC results of fluoryram and its metabolites in μg/L for the ases as essent — Tier 2a 2, and all application

Use pattern		Floopyram		Trifluoroacetic acid
Vines I, 2×50	a.s./hac	0.457	0.041	5.818
Vines II, 2×50	g a.s./ha	\$ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	0.021	3.644

Maximum FQCUS PELMOCECgw 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, 250 g a /ha	0.176	0.046	5.965
Vines 11, 2×50 pa.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	3.130
Vines II, 2×50 g a.s./ha	0.015	0.005	£405 \$\times^{\tilde{\chi}}

Biennial application

Table 9.2.4.1-35: Maximum FOCUS PEARL PEC results of fluodyram and its metabolites in ug/L for the uses assessed – Tier 2a 2, bigonial application

		7	(O>)	^	~ "	√ n	37
Vines I, 2×50 g a.s./ha	\$0, 00	- V		30 /019 🗸		°⊋.317 ∜	,
Vines II, 2×50 g a.s./ha	$\mathbb{O}_{0.02}$	2 7 Č		70.0190°	0	√, 1.46 3 √,	A. °

Table 9.2.4.1-36: Maximum FOCUS PELMO PEC results of fluopyrang and its metabolites in ag/L for the uses assessed—Tiev 2a 2, piennial application

Use pattern	Q S Flu	kopyrano		Prifluoroacetic acid
Vines I, 2×50 g a.s./ha		0.058	√ 0.10√9 Ç	3.344
Vines II, 2×50 g a.s./ha			0.010 °C	2.051

Table 9.2.4.1-37: Maximum FOCUS MACRO PECgw results of fluopyram and its metabolites in μg/L for thouses assessed Tier 2a 2, be mial application

Use pattern Shaper am Shuopyram Shuopyram-7-hydroxy	Trifluoroacetic acid
Vines I, 250 g a.s./ha <0.001 <0.001	1.581
Vines II, 2×50 g a.s./hg <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 – Ter 2a 2 triennal application

Vines I, 2×50 g a.s./ha	4 ~	0.030	0.010	1.623
Vines 11, 2×50 g a.s. Tha	\$ 7	Q 20014	0.005	0.977

Table 9.2.4.1-39: Maximum FOCUS PELMO PECgw results of fluopyram and its metabolites in μg/L for thouses assessed Tier 2a 2, triennial application

Use pattern A	Fluopyram	Fluopyram-7- hydroxy	Trifluoroacetic acid
Vines I, 250 g a.s./ha	0.031	0.011	2.187
Vines kt.,2×50 g a.s./ha	0.015	0.006	1.382



Maximum FOCUS MACRO PEC $_{gw}$ results of fluopyram and its metabolites in $\mu g/L$ Table 9.2.4.1- 40: 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	5.520

Predicted environmental concentrations in groundwater (PEQw) for fluory ram in letture (soft 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 soft-bound cultivation.

Since FLU + TFS SC 500 is applied to Lettuce in relevant entry path.

PEC_{gw} for trifloxystrobin and its metabolites

No groundwater assessment was required for triflogystrobin 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_{sw}) are presented below.

Endpoints for PECsw

Table 9.2.5- 1: Modelling input parameters for <u>fluopyram</u> and its metabolites FLU-7-OH and FFA (FOCUS sw)

	1	,	
Compound	Fluopyram	F uopyram-7- by droxy	Trifluor@cetic acid
		(FLU-7-QH) °	(TFA)
Molecular mass (g/mol)	396.72	4/2/.72	114.02
Water solubility (mg/L)	19 (20°C)	33.95 (25.75)	\$500000 (20°C)
Saturated vapour pressure (Pa)	1.2 E-6 (20°C)	1,\$5 E-9,(20°C)	1.0 2-6 (2002)
Koc (mL/g)	232	Ø \$ \$00.2 \$\frac{1}{2} \frac{1}{2} \	\(\tilde{\pi}\) \(\tilde{\pi}\)
Kom (mL/g)	139,7	58 2 0	\$\tilde{\pi}\0*
1/n	Ø:8432 ® *>	0.2292	
Plant uptake factor TSCF			
Wash off factor from crop (1/m)	\$ '500 \$ \$ \$	500	♥ 50
DT ₅₀ in soil (d)	298.8 (figld)	17.53 (lab)	1000*
DT ₅₀ in water (d)	909 (Step 1,2) 71000 (Step 3,4)	0 1000*	1000*
DT ₅₀ in sediment (d)	969 (Step 7,2) 1000* (Step 3,4)	\$ \$000*	1000*
DT ₅₀ in total system (d)	909	1000	1000
DT ₅₀ on canopy (d)	10", %,	\$\ \tilde{\Phi} \ \tilde{\Phi} \ \tilde{\Phi}	10*
Maximum occurrence (%) Water/sectionent: Soil:		\$ 25° 05°	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 modelling approach

Calculation of FEC values for the active substance according to FOCUS

FOCUS_{sw} is 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 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.

<u>Step 3:</u> 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-rech 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 pestiondes used in Soil-less cultivation
- Surface water exposure assessment for pesticides used in soil bound oultivation
- Leaching assessment to ground water for pesticides used in Soil-bound curivation

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

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

A summary of important substance input parameters is given in Table 9.2,3, 23

Data Point:	KCP 9.25701
Report Author:	
Report Year:	2021
Report Title:	Floopyrand FLU Core Pecgw PECswill EUR - Modelling core info
	decument for groundwater, surface water and soil risk assessment in Europe
Report No:	EnSavQI-007
Document No:	M-7-3252-63-1
Guideline(s) followed in	none & F iy & A
study:	
Deviations from corrent	Current guideline: not applicable
test guideline:	
Previous evaluation: O	No, not previously subprixted
3	
GLP/Officially recognised testing	No. 10t conducted under GEP/Officially recognised testing facilities
facilities:	
Acceptability/Reliability:	Yes Y

Executive Sommary

This document commarises 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- hvdroxy	Trifluoroacetic acid
Molar mass	(g/mol)	396 72	412.72 A	11462
Water colubility	(g/III01) (mg/L)	10	33.75	500000
Koc	(mg/L)	232.1	100 2	F ₋₁₀
Noc Degradation	(IIIL/g)	232.1 &.	100.2	North-100
Soil	(days)	208.08	1853	1800 0
Total gratem	(days)	298.08 1	2000	
Water	(days)	909	(1000 S	\$ 2000 \$ \$ C
Valei Sadimant	(days)	90 %	1000	#1000 1. 1000
May a sayman sa	(days)	70,3		
Water / sadiment	(0/)	100 %		
Soil	(%)	100	5.8	14.8
Parameter Molar mass Water solubility Koc Degradation Soil Total system Water Sediment Max occurrence Water / sediment Soil				



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

Parameter	Unit	Parent	Metabolite	Metabolite
Substance		Fluopyram Tier 1	FLU-7-	TFA Tier
SWASH code		FLU	hydroxy_Tier1	TF
			70H	4 2
General			7	
Molar mass	(g/mol)	396.72	412.72	, O 14.02
Water solubility (temp.)	(mg/L)	19.0 (20 °C⁄⁄⁄⁄₂	33.75 (Q5 °C)	500000 (200°C).√
Vapour pressure (temp.)	(Pa)	1.2E-06 (20°C)	1.55E (20 °C)	©1E-06020 °C)
Crop processes			S \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	
Coefficient for uptake by plant		a C		
(TSCF)	(-)		l & m° ×	
Wash-off factor	(1/m)	Q0 50	\searrow \mathscr{C}_0 $\overset{\sim}{\searrow}$	
Sorption Sorption	(1,111)	W Pa ·		
K _{OC}	(mL/g)	1 0 230 i . V	\$\tag{2}\tag{1000}	04
K _{OC} K _{OM}	(mL/g)	1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	10002 58.1	
Freundlich exponent (1/n)	(_) «/	\$ \$437 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	A 9292	
Transformation		# W.OT. / /	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
Transformation D _{T50} in soil		1 () 200 INO S		\$\tag{7}\tag{1000}
	(daQs)	1 2 20 10 V	1/02	
temperature		p	0.633 1000 1000 1000	\$ 20
moisture content (pF)	(Dog(cm))		0.63	P 75402
formation fraction in soil			1 0 0.65465 C	0.5402
DT ₅₀ in water	(days)	10000	1000	0.5402
temperature	((°C)	20	~ ~ 2 0 ~ \$	20
formation fraction in water	(-) N		1000 5 20 5 20 5 1000 5	<u>-</u>
DT_{50} in sediment	(days)	1000	1000	1000
DT ₅₀ in sediment temperature formation fraction in ediment DT ₅₀ on canopy	/ (% C)		20	20
formation fraction in Sediment	(-)	y ,\$7 - \$\dots	0°- 4"	-
DT ₅₀ on canopy	(dayş¶	1900 .0	10	10
Exponention the spect of				
moisture	0 4	o' 47 ».		
PRZM and TOOSWA Walker		0.75	Ď	
exn)	\$ (-) <u>4</u>	0.75	₩ 0.7	0.7
MACRO (calibrated value)	J (Dor"		0.49	0.49
Effect of remperature @ S	(1/ K)	~ , O, , , , , , , , , , , , , , , , , ,		
TOXSWA (molar activat. energy)	₩J/mol	65.4%	65.4	65.4
MACRO (effect of temperature)	(1/ K)	0.09	0.0948	0.0948
$PRZM (Q_{10}) \qquad \qquad$	i `#	2.58	2.58	2.58
	' , 💍			<u> </u>
MACRO (effect of comperature) PRZM (Q ₁₀)		2,58		
A TO)" <u>"</u> Q	B. W.		
	, O			
	A			
	m _ Ć			
	y Q			
	, Q)	K .		
		Q,		
	*			
	y Q			
	,			
T G				



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_{sw} alues as presented below are interim values and are therefore subject to charge 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:

KCP 9.2.5/02
2021
Fluopyrant (FLU) and metabolite PEC weed FOCUS FOR (tight) - Use in
apples, spring gereals, winter reseals and vines on Europe
EnSa-21-0067
M-763460-0Y-1
Current guideline: not applicable
No, not previously submitted
No, not conducted under GLP/Officially recognised testing facilities
Yes Z

«» «»	
Data Point:	KČP 9. 25/03 O
Report Author:	
Report Year:	202\$ \$ \$ \$ \$
Report Title:	Flüopyram (FLU) and metabolite. PECsw, sed FOCUS EUR (tier 1) - Use in
	apples, spring coreals, conter coreals and vines in Europe
Report No:	EnSa 21-0069
Document No:	M-203417-01-1
Guideline(s) followed n	none of the second seco
study;	
Deviations from current	Current guideline: not applicable
test guideline:	
Previous evaluation	No, not previously submitted
GLP/Officially	No pot conducted under GLP/Officially recognised testing facilities
recognised testing	
facilities:	
Agreptability/Reliability:	Yes

<u>Please note</u>: 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 employers 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 22.5-4.

Table 9.2.5-4: Application pattern used for PECsw galculations of Juopyram

Crop	BBCH stage	Rate [g a.s./ha]	Interval FOCUS crop Season Crop Giver
Vines	53 - 73	2 × 56 ×	Vines, late (May May) application (Vines / late) (Vines / late) (Jun. Sep.)

Substance input parameter are summarise in Table 9.2 2 and Table 9.2.5.

For the use in grapes in addition to EOCUS Step 32 values, FOCUS Step 3 values were calculated for the active substance fluopyrand and its metabolites fluopyrand and trifluoroacetic acid (TFA). In FOCUS Step 3, the application date for each scenario is determined by the Pesticide Application Timer (PAL), which is part of the FOCUS SW Scenarios. The user may only define an application time window. The actual application date of the policy is the part in such a way that there are adjected 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 window, the above rules are step-wise relaxed. Information on application dates can be found in Table 9.2.5.3.



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

r r		- С С С С С С С С С С С С С С С С С С С		
Vines	, early	Vines	s, late	
Air blast (2 – appl.	foliar linear, 4 cm)	Air blast (2 – appl.		
3	7	, ** *		
PAT start/end date (Julian day)	Application date	PAT Start/end date (Julian day)	Application	
12-Mar/18-Apr (71/108)	14-Mate 09-Apr	30-May/06-Jul (150/57)	30-May 06-July	0
19-May/25-Jun (139/176)	11-May 12-Jun	199ul/25 Aug (200/237)	28-Jul 20-Aug	
14-May/20-Jun (1334)(771)	20-May 27-May 4	09 Aug/1 Sep (221/258)	09-Aug 14-Sep	
24 May/30-Jun (144 181)	01-Jan 160an	14-Aug/20-Sep (226/263)	14-Aug 28-Aug	
(0-May(13-Jun (127/164)	07-May 27-May 27	(210/247)	31-Jul 13-Aug	
	Vines Absolute Air blast (2 – appl. 3 7 PAT start/end date (Julian day) 12-Mar/18-Apr (71/108) 19-May/25-Jun (139/176) 14-May/20-Jun (133/771) 24-May/30-Jun (144/181)	Absolute Air blast (2 – appl. foliar linear, 4 cm) 2 37 7d PAT start/end date (Julian day) 12-Mar/18-Apr (71/108) 19-May/25-Jun (139/176) 14-May/20-Jun (133/171) 24-May/30-Jun (134/171) 27-May 27-May 24-May/30-Jun (144/181) 16-Jun 16	Absolute Air blast (2 – appl. foliar linear, 4 cm) 2 37 7d PAT start/end date (Julian day) 12-Mar/18-Apr (71/108) 19-May/25-Jun (139/176) 14-May/20-Jun (134/171) 20-May 20-May (134/171) 21-May (134/	Absolute Air blast (2 – appl. foliar linear, 4 cm) 2 37 7d PAT Start/end date (Julian day) 12-Mar/18-Apr (71/108) 19-May/25-Jun (139/176) 19-May/25-Jun (139/176) 20-May 12-May 12-Ma



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

FOCUS Step 1, 2 PECsw and PECsed for fluopyram following single multiple application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- spring -- 2050 g **Table 9.2.5-6:** a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PECsw Dominant entity 21d-PECsw,twa Max PECsw (μg/L)** (μg/kg)*
Step 1	-	28.1 A
Step 2		
Northern Europe	Mar May (Spring)	3.98
Southern Europe	Mar May (Spring)	5.96 7 RunOff 7 13.5

Single applications are marked.

FOCUS Step 1.2 PECs and PECsed for fluopyram following single/multiple **Table 9.2.5-7:** application(s) of FLU TFS SC 500 to grapes (modelling use vines -- summer -- 2×50 g a.svha, 7d jint.)

Scenario FOCUS	Waterbody	(μg/ L)*	// ///// // // // // // // // // // //	24 d-PEC _{sw,twa} (μg/L)**	Max PEC _{sed} (μg/kg)*
Step		5 28.9 N	RunOff	27.3	63.8
Step 2					
Northern Europe	Jun Sep.	3.96	Drift [©]	3.78	8.82
Southern	Jun Sep.	24 96 O	P	4.77	11.1
Europe	(Summer)	4.96	PeinOff	7.//	11.1

Single applications are marked.

TWA interval as required by ecotor

Single applications are marked.

*** ADWA interval as roquired by ecotor.



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

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

Scenario FOCUS	Waterbody	Max PECsw (μg/L)*	Dominant entry route	21d-PECo, twa (µg/L)**	Max PECsel
Step 1	-	1.77	-Ö	€1.76	\$\tag{\tag{\tag{\tag{\tag{\tag{\tag{
Step 2			A.		
Northern Europe	Mar May (Spring)	0.141		0.140	0.1426 C
Southern Europe	Mar May (Spring)	0.282		J 0.280 O	2283

Single applications are marked.

FOCUS Step 1, 2 PECswand PECsed for fluopyram Table 9.2.5-9: single/multiple application(s) of FLU+ TFS SC 500 o grapes (modelling use vines -summer -- 2×50 g a.s./ha, 7d/nt.)

Scenario FOCUS	Waterbody	Max PEC	Dominant entry route	21d-PEC, twa	Max PEC _{sed} μg/kg)*
Step 1		1.75	\$\frac{1}{2}\times^2\t	1.76 0	1.78
Step 2			J' J'	Ŏ Ļ	
Northern Europe	Jun Sepo				0.142
Southern Europe	Ulun Ken	0.212	route	© 0.210	0.212
* Single ** TWA i	applications are marken nterval as required by	ecotor 6		*	
	applications are marken terval as required by	ecotox of the second of the se			

TWA interval as required by ecotox



Trifluoroacetic acid (TFA)

FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for trifluoroacetic acid following single/multiple Table 9.2.5- 10: application(s) of FLU + TFS SC 500 to grapes (modelling use vines -- spring -- 250 g a.s./ha, 7d int.)

		M DEC	Б	211000	Max PEC
Scenario FOCUS	Waterbody	Max PEC _{sw} (μg/L)*	Dominant entry route	21d-PECa,twa	Max PEC and Pig/kg/
Step 1	-	1.42	-8	A.41	<0.00)
Step 2					
Northern Europe	Mar May (Spring)	0.113		0.112	\$0.00° *0
Southern Europe	Mar May (Spring)	0.226		0.224	\$0.001 \(\tilde{\tilie}\tilde{\tilde{\tilde{\tilde{\tilde{\tilde{\tilde{\tilde

Single applications are marked.

FOCUS Step 1, 2, PEO Table 9.2.5- 11: 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	Dominant entry route	21d-PECan,twa	Max PEC _{sed} (ug/kg)*
Step 1	- "	1.42		1.41	< 0.001
Step 2			5 5 a	0 4	
Northern Europe	Jun Sep Summer				<0.001 *
Southern Europe	Olyn Sen V	0.169	route	0.168	<0.001 *
* Single ** TWA i	applications are marked nterval as required by	0.169			

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 fluop 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:

loadings via	a all relevant entry	routes.
Fluopyram Table 9.2.5-	12: FOCUS St	routes. The reported The wind and The reported The wind and The wind and The wind and Pecsed for fluopyram following single/monttiple (s) of FLU + TFS SC 500 to grapes (modelling use vines early 2x0.05 7d int.) Max Pecsed For fluopyram following single/monttiple (s) of FLU + TFS SC 500 to grapes (modelling use vines early 2x0.05 7d int.) Max Pecsed For fluopyram following single/monttiple (s) of FLU + TFS SC 500 to grapes (modelling use vines early 2x0.05 7d int.)
	kg a.s./ha,	7d int.)
Scenario	Waterbody	Max PECsw & Dominant entry 21d-PECsw,twg Max PECsed
FOCUS	water body	(µg/L)* O Croute (µg/L)** (µg/kg)*
Step 3		
D6	Ditch	0.866 Spray drift 0,124 0 0.754 0
R1	Pond	0.057 Runoff 0.051
R1	Stream	1.08 Spray drift 5 0046 0.501
R2	Stream	\$\infty 0.840 \cdot * \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
R3	Stream 🛴 🧞	©.887 * Spray drift 0.028 0.203
R4	Stream	0.617 Spray drift 0.038 0.288 *

Single applications we marked.

sw and PEC of for thropyrain following single/multiple Table 9.2.5- 13 application(s) of FLU+ TFS SC 500 for grapes (modelling use vines -- late -- 2×0.05 kg a.s./ha 7d into

Scenario FOCUS	Waterbody Max PEOsw (µg/L)*	Dominant entry	21d-PEC _{sw,twa} (μg/L)**	Max PEC _{sed} (μg/kg)*
Step 3				
D6 🚄	Ditch 1.14	Soray drift	0.536	1.67
R1 🝣	Pond Q 0.046	Spray drift	0.041	0.233
RY.	Stream 0.612 *	Spray drift	0.006	0.084
R2	Stream 0.843	Spray drift	0.013	0.157
R3	Stream 6.946	Spray drift	0.101	0.591
R4 🚜	Stream O 2 1.10	Spray drift	0.056	0.569

Singre applications are marked.

TWA interval as equired by ecoto

TWA internal as required by



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 -- 2×005 kg a.s./ha. 7d int) kg a.s./ha, 7d int.)

Scenario FOCUS	Waterbody	Max PECsw (μg/L)*	Dominant entry route	21d-PECsw,twa	Max PEC
Step 3			T.	Q'	
D6	Ditch	0.033	, O -	0.011	@036 O
R1	Pond	< 0.001	- ~	©0.001Q \	○ <0.001
R1	Stream	0.016	,	<0.001	Q 004 S
R2	Stream	0.011		% .001	₹ 0.00 4 ₹
R3	Stream	0.008		<0.00	0.662
R4	Stream	0.013	V - , Y ,	O <0.001 S	Ø.005

Single applications are marked.

FOCUS Step 3 PECsw and PECsed for FLU-7- Off following single/multiple Table 9.2.5- 15: application(s) of FLU + FFS S6 500 to grapes (modelling use vines) late -- 2×0.05 kg a.s./ha, d int.)

Scenario FOCUS	Wate Body	Max PECan µg/Ly	Dominant entry	201-PECw,twa (µg/J)**	Max PEC _{sed} (μg/kg)*
Step 3	Ditch				
D6	la. Diffeh	©0.017_1 © <0.007 *	7 5- a.	© 0.006	0.020
R1	Pond Stream	\$\footnote{\chi_0.061} \text{*}	7 - 10	<0.001	<0.001 *
R1	Stream	≈ 0.001 6 * .	J 4- 1	< 0.001	<0.001 *
R2	Stream ≼	&°0.01√	° - 5	< 0.001	0.004
R3	Ø Stream	0.010	S S	< 0.001	0.003
R4	Stream S	0.640 0")	< 0.001	0.005
* Single ** TWA i	Stream Stream Sapplications are marked nterval as required by	ecotox, of the second of the s			

Sing@applications ar@marked

TWA interval as required by ecotor



Trifluoroacetic acid (TFA)

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

Scenario FOCUS	Waterbody	Max PECsw (μg/L)*	Dominant entry route	21d-PEC twa (µg/L)**	Max PECsoc
Step 3			Ö	O'T	
D6	Ditch	1.03	Z -	0.955	0308
R1	Pond	<0.001 *	<u> </u>	<0.001 O	\$ \displaystyle \dintforus \displaystyle \displaystyle \displaystyle \di
R1	Stream	0.006	Q - >	. 0.001 N	° <0.601
R2	Stream	0.004		<0.001	₹Ø.001 [*]
R3	Stream	<0.001		0.001	0.061 °°°
R4	Stream	0.005		<0.001 &	<0.001

Single applications are marked.

FOCUS Step 3 PEC and PEC sed for TF Afollowing single/multiple application(s) of Table 9.2.5- 17: FLU + TES SC 500 to grapes (modelling use vines -- late -- 2×0.05 kg a.s./ha, 7d int.)

Scenario FOCUS	Waterbody Max PECsw Dominant entry (pg/L)* rouge	21d-RECsw, www.	Max PEC _{sed} (μg/kg)*
Step 3			
D6	Ditch 0.443	b ≪0.380	0.204
R1	$Pood = \{0.001, **\}$	0.001	<0.001 *
R1	Stream < <0.000 +	<0.001	<0.001 *
R2	Stream \$\infty \leq 0,001 \infty \ \infty \ \ \ \ \	< 0.001	<0.001 *
R3	Stream 50.004 7 0 0 - 5	< 0.001	< 0.001
R4	Stream 5 0.007 5 5	< 0.001	< 0.001

Single applications are marked.

TWA interval as required by ecotox

^{**} Single apprications are marked.
TWA interval as required by ecolox



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 crops inesplate). The reported PEC_{sw} values represent loadings via all relevant entry routes

Fluopyram

Table 9.2.5- 18: PEC_{sw} values for fluopyram, following spigle/multiple opplications (spot FL1) + TFS SC 500 to grapes according to surface water Step 4 (modelling use ones - Parly 2×0.05 kg a.s./ha, 7d int.)

				<u> 2</u> 0		<u> </u>	0 م		0 n
PECsw (μg/L)	Scenario		Ç		Step 41	uopyram			
Nozzle	Vegetated strip (m)	None	None	None None	None	uopyram 10 m	20 m		
reduction	No spray buffer (m)	0 m	\$\frac{1}{2}\text{m} \times \frac{1}{2}\text{m} \text{F}	10 m	26 m	10 m	20001		
None	D6 Ditch	0.860	0.522	0.764 s	Š0.464€	0.464	J. 464		
50 %		0.46\$	Q464	© 0.4640°	0.494	J. 464 C	0.464	°~	
75 %		Q\$64	0.464	0.464	J.464	Q 0.464	0364	&	
90 %		0.464 ₂	0.464	Q 464	0.464	0:464	©0.464	<i>y</i>	
None	R1 Pond	0.059	0 3064 <u>s</u>	© 0.04£	0,027	Ø.033,	0,046		
50 %	∠	Q. 0 35	\$ 0.0390°	0.27	, 9.020 K	0.019	. 0.0 09		
75 %	S .	0.024\$	0.026	\$.020 X	0.017	0012	∜0.006		
90 %	J. Š. O	0.048	40.019 A	, 0.0LF	0.015	\$0.008	0.004		
None	& Stream	1.08	¥ 1.086°	1.98	1.08	0.474	0.245		
50 %		€ 1.0&	1.08	J1.08 S	1.00	£474	0.245		
75 %		1598	J.08	1.08	£.08 ~	©0.474	0.245		
90	, Ø	.D.08	1.08,	, P.08	1.08°	0.474	0.245		
None	R2 Stream	0.840	Q \$12	~0.514°	0.574	0.232	0.121		
50 %		Q\$14	©0.514	0.544	P.514	0.232	0.121		
75 %		0.514×	0.5.4	2514	© 0.514	0.232	0.121		
90 % 🦼	C	0.50	Ø\$14 €	0.51	0.514	0.232	0.121		
None	R3 Stream	© 87	$\mathbb{Q}_{0.64}$	0234	0.165	0.234	0.082		
50 %		4 0.443	0.223	×9.165	0.165	0.117	0.041		
75 %	Ô	0.232	0.465	0.165	0.165	0.072	0.037		
90 %	L	Ø:165 ~	0.160	0.165	0.165	0.072	0.037		
None	R4 Stream	0.617	0@27	0.527	0.527	0.230	0.119		
50 %		0.527	0.527	0.527	0.527	0.230	0.119		
75.25	Ž A.	~©.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.)

	2.0.031	xg a.s./11a,	, a me.,					•	, Ç
PECsw (μg/L)	Scenario				Step 4 fl	uopyram	To To	Š.	
Nozzle	Vegetated strip (m)	None	None	None	None	10 mc	20 m		
reduction	No spray buffer (m)	0 m	5 m	10 m	20 m	19 , m	20 m@		
None	D6 Ditch	1.14	0.684	0.300	0.306 A	0.3060	0306		
50 %		0.568	0.341	203 06	0.300%	Q. 3 06	0.306 C)	
75 %		0.306	0.306	(0.30 6)	0,3006	₹ 9 .306€	0.306	** '	C ⁷
90 %		0.306	0.306	0.306	Ø.306	0.3 %	0.306	4 4	&°
None	R1 Pond	0.046	0.054	~9.029,^	0.015	Ø\$Q29	0.015		Ø,
50 %		0.023	® 627	y"0.01 & "	Q: 9 07	O.015	0.697		B.
75 %		0.012	0.013 0,005	Q: Q 07	90.004 T	0.00	\$004 _E	V B	
90 %		0.005	0,005	0.003	0.00	6003	O.004,		
None	R1 Stream	0. @ /2	446	0.162	J© 057	$\sqrt{2}$ 0.162	0337	&	
50 %		40.306 ₄	0.22\$	Q .081	0.028	0,081	©0.028	0	
75 %	2	0.15°	0 P12	©0.040	0.016	0.040	0.014		
90 %	<i>∀</i> ,	0.061	رُّهُ 0.045 في الم	0.096	. 6 .016 &	, 0.016	05006		
None	R2 Stream	0 .843	0.645	£234 ×	J 0.234	0323	LÖ.078		
50 %		0.429	.0,307 _~	0.2340	0 3 4	LO.111@	0.055		
75 %		0.234 \$	0.234	0.234	V.234	0. 106	0.055		
90 %		$C_{0.234}^{\circ}$	0.23/4	Ø.234	0.23	@1 06	0.055		
None 🔊	R3 Stream	0.248	#946 C	0.946	0946	©0.428	0.224		
50 🎉 🥤	K3 Stream	6 946 '	© 0.946\	0346	0.9460	0.428	0.224		
75 %		Ç 0.946	0.046	ۯ.946&	0.946	0.428	0.224		
90 %	Q A	0,46	40 .9464	0.946	2 946	0.428	0.224		
None	R4 Strom	J.10.	1.10	\$\\ \Did 10	T1.10	0.494	0.257		
50 % 🦼			QIO	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	1.10	0.494	0.257		
75 %	_	1 0	W1.10	1,10	1.10	0.494	0.257		
90 🚿		4 7.10°	1.40	~9.10	1.10	0.494	0.257		

^{*} Maximum values coming from multiple applications are marked in italics



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

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

							O ₈		<u> </u>
PEC _{sw} (μg/L)	Scenario				Step 4 F	LU-7-OH			
Nozzle	Vegetated strip (m)	None	None	None 4	None	100m	20 m Č		
reduction	No spray buffer (m)	0 m	5 m	104	20 m	10 m	204m		
None	D6 Ditch	0.033	0.033	®.033	0.033	Q \$33	0.033	*L)*	
50 %		0.033	0.033	V 0.03	0.7933	0.033	0.003	7/	O °
75 %		0.033	0.033	0.033	Ø.033	0.033	0.033		Z,°
90 %		0.033	0,633	Ø.033	0.083	0.033	0.033	. O	Z,
None	R1 Pond	< 0.001	Ø.00 k	7 < 0.QH	≪0,001 ₄	Q0.004	<0.0001		2
50 %		<0.001	0.00y	<0,001 ·	\$0.0Q10	<0.001	\$0.001		
75 %		<0.00 🕏	< 0.001	\$\int_0.00\tag{\int}	<0.001	3 .001	(0.0 %	~\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	
90 %		<p\$01< td=""><td>0.001</td><td><0.691</td><td>Ø.001</td><td>Q.0.00P</td><td></td><td>4</td><td></td></p\$01<>	0.001	<0.691	Ø.001	Q.0.00P		4	
None	R1 Stream	40.016 _k	0.076	Q ,016	0.016	0.007	©0.004		
50 %	~	0.018	6 716	0.016	0,016	\$3.007 C	0.004		
75 %	\ \L_1	Q:016	<i>الله 0.016</i>	0:946	©.016 &	0.007	, Ø 0000004		
90 %		9.016C	0.02/6	2.016	0.016	0007	\$0.004		
None	R2 Tream	0.04	× 0 011 ~	0.01	00011	\$0.005@	0.003		
50 %		0.011	√ 0.01 √	Q. OH 1 ,	0.011	0.065	0.003		
75 %	ÕŞ,	© 0.011	0.071	9 .011	$0.0 \hat{\Omega}$	₄ 0.005	0.003		
90 %		0,011	7 011	0.011	Q011 ~	©0.005	0.003		
None	R3 Stream	\$ 0008 °	0.008	.0008	₩0.008 [©]	0.003	0.002		
50 %		0.008	2008	\$0.008\$\frac{\$\psi}{2}\$	0.008	0.003	0.002		
75 %		0.008	0.008×	0.008	2 008	0.003	0.002		
90 %		0.008	0,008	.0008	0.008	0.003	0.002		
None ,	R4 Stream	0.03	Q 013	0.01	0.013	0.006	0.003		
50 %	, Ø	Ø13	©0.013	0.073	0.013	0.006	0.003		
7,5 %		\$ 0.013\frac{1}{2}	0.633	D.013	0.013	0.006	0.003		
90 %		0.073	P.013 6	0.013	0.013	0.006	0.003		
	·		(a).	7	I	L	L	1	L

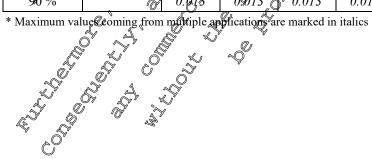




Table 9.2.5- 21: PEC_{sw} values for FLU-7-OH, following single/multiple applications(s) of FLU + TFS SC 500 to grapes according to surface water Step 4 (modelling use vines -- late -- 2×0.05 kg a.s./ha, 7d int.)

								0	
PEC _{sw} (μg/L)	Scenario				Step 4 F	LU-7-OH			
Nozzle	Vegetated strip (m)	None	None	None	None	10 mg	20 m		
reduction	No spray buffer (m)	0 m	5 m	10 m	20 m	10, m	% 1		\$ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
None	D6 Ditch	0.017	0.017	0.03	0.017 &	0.017	0017		
50 %		0.017	0.017	Ø617	0.01%	Q. Q. 7	₩.017 C		
75 %		0.017	0.017	0.01 7	0,007	\$0.017	0.00	, A.	Ü,
90 %		0.017	0.017	0. QJ 7	Ø.017	0.00	0.017	¥ 3	L°
None	R1 Pond	< 0.001	<0;001	×0.001^	<0.001	<0.001	0.001		Q [†]
50 %		< 0.001	20 .001,	×<0.004	< 0 .001	Ø0.001	<0.001		Ž.
75 %		<0.001	5¥0.0 % ¥	<0.001	\$0.0Q10°	<0.001	© .001		
90 %	-	<0.000	< 0.001	<0.004	<0.001	6.001	O<0.000		
None	R1 Stream	<0.001	6 0.001	<0.001	\$0. 001 \(\)	0.00 P	< 0.001	(L)	
50 %		₹0.00 k	<0.00	<0.001	~0.00 L	<0.001	⊗0.001 °	D'	
75 %	•	Ø<0.00₽	< 9 .001	\$0.001	< 0.001	Ø.001	×<0.001		
90 %	, °y	<0.001	&<0.00	<0.001	6 0.0014	<0.001	< 6 001		
None	R2 Stream	Ø.011	0.041	D 011 ×	J0.011	0305	L. 0.003		
50 %		0.019	Ø811 _~	0.0HQ	0H1	L0.005@	0.003		
75 %		0.011 \$	0.01	0,0,1	0.011	0.005	0.003		
90 %		O.011	0.01/1	20 .011	0.00	@ 005	0.003		
None	R3 Stream	0.010	20 010 C	0.016	QQ10 ×	©0.005	0.002		
50 %		6 5010 '	\$ 0.010	0510	0.0100	0.005	0.002		
75 %		(0.010)	0.010	ۯ.010&	0.040	0.005	0.002		
90 %		0,000	49 .010×	0.010	20 010	0.005	0.002		
None	R4 Strom	Ø.017.	0.00	, Ø 17	©0.017	0.008	0.004		
50 % 🧳		0.02	Q Q017	\$0.01 <i>7</i>	0.017	0.008	0.004		
75 %		0.017	Ø0.017	0.047	0.017	0.008	0.004		
90 %		3 0.017×	0.04	\$2017	0.017	0.008	0.004		
	- N N		· (////	· * */	1	1			

^{*} 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:	
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite: PECsw after applieution in greenlouses using
	greenhouse emission model (GEM-3.3.2) - Use in Lettuce in the Netherlands and
	Europe V V V
Report No:	EnSa-21-0068
Document No:	M-763353-01-1
Guideline(s) followed in	not applicable
study:	
Deviations from current	Current guideline: not applicable
test guideline:	
Previous evaluation:	No, not previously submitted of O
GLP/Officially	No, not conducted under GLP Officially recognised testing favilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q

Methods and Materials:

Predicted environmental concentrations of surface water (PEC, w) were estimated after use in high-tech greenhouses in the Netherlands and Europe. The exposure assessment model GEM 3.3.2 (Greenhouse Emission Model 3.3.27 was used. It contains greenhouse scenarios, for both soil-less and soil-bound cultivation. Only soft less cultivation was considered here for the use of FLU4 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,

The assessment was carried out for the active substance fluopyram and its metabolite trifluoroacetic acid (TFA) in soil-less cultivation in settuce. The soil metabolite thuopycam-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 GPM parameters, differing from GEM default values are summarized in Table 9.2.5-23. The use of fluopyram was assessed according to the Good Ogricultural Practice (GAP) as summarized



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)	(-)	\$\frac{1}{2}\frac{9}{2}
Soil-less:	Lettuce; Lactuca	2 × 200	7	12 40	15.0 + 22.01.
Lettuce	spp		Ž	(Jan - Dec)	15.02. +22.02. 15.03. +22.03 15.04. 22.04
		a"(15.05. + 22.05. 15.06. + 22.06. 05.07. ± 22.07
					15.08 + 22.08. 15.09. + 22.09. 15.10. + 22.10.
					95.11, \$22.1167
	3				08.04. + 15.04. 22.04. + 29.04.
					08.f _{0/} + 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-teck greenhouses are relatively independent of the season. Additional calculations were performed days before and after the date-of-use that resulted in the highest PEC for parent and metabolitie.

For the soil-less assessment, the scenarios with and vithout 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
General Parameters			
Molar Mass	g/mol	396.72	\$\int 114.02\forall \text{\$\}\$}}}\$}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}
Water Solubility	mg/L	19.0 (20°C)	500000@20°C)
Vapour Pressure	Pa	1.2E-06(20°C)	1.0E ₅ 0©(20°C)
Plant uptake factor (TSCF)	-	(h) 0 4	
Sorption			
Kom	mL/g	134.7	1000
Freundlich Exponent	_	(a) 0.8432	
Degradation			1000 1000 1000 1000
Soil/Substrate	d 《	29 8.7 8 ~ 🗸	1000
Water	d 🐒	298 08 1900 1000 100	1000
Sediment	d ◎		1 m² ~1000 4
Crop Canopy	d		0 10 0 K
Activation Energy ^A	kJ/mood ≥ °	\$\times_\	65.48
Formation fraction			Soil: 0,5402
	Q (\(\sqrt{\sq}\}}\sqrt{\sq}}}}}}}}}}}}} \end{\sqrt{\sq}}}}}}}}}}}}}}}} \end{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sq}\eqs}}}}}}}}}} \end{\sqrt{\sintinitita}}}}}}}} \end{\sqrt{\sqrt{\sint{\sint{\eqs}}}}}}}}}} \	1000 x 7 10000	Soil: 0,5402 Water: 2 Sediment 2 Recipiulation water: 2
			Seatimen@2
			© Recipculation water: 2
GEM specific parameters			
Octanol-water partitioning	, · · · · · · · · · · · · · · · · · · ·	2060 ⁰⁰ , ©	© 0€002554
coefficient Pow		Ø og Pow = 3.3) ✓	$\log Pow = -2.7)$
Kom substrate = Kom soil		L 134.7 V X	
DT_{50} substrate = DT_{50} scil DT_{50} in recirculation vater / disinfection tank = T_{50} horrolys DT_{50} on greenhouse floor	moL/g of d	298.0	1000
DT ₅₀ in recirculation vater /e		7 D 1000	1000
disinfection tank = ∇T_{50} hydrolys	is V		
DT ₅₀ on greenhouse floor	√	100, default	_
I I in graan belied our D	an w	1.76 (=20.78 hour \$\mathcal{Q}\$12	100
		hour days	
Activation Energy greenhouse are Activation Energy recirculation	KJ/IIIOI	45 7	45
Activation Energy recirculation water D	kJ/mool &		75

Α used for most 10,750 values, i.e. son, surface water and sediment

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 was taken into account for modelling purpose.

For soil-less cultivations, the plant whake Sestimated by the transpiration stream concentration factor (TSCF) evaluated by Briggs Briggs focused on the TSCF dependant on the octanol/water partitioning coefficient Pow or log Poo of a compound.

Fluopyson is described to be not prone to hydrolysis. Therefore, the DT₅₀ in recirculation water and in disinfection tank was set to 1000 d.

В Photochemical oxidative degradation in air used for Diff greenhouse air

 $[\]mathbf{C}$

used for DT 50 recirculation water



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.

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.

Species Fluopyram Fluopy	GEM scenario			Lettuck	O Q C
Species Fluopyram		0	% &		Q 95% TEA
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.	Species/	Fluonyram		Fluor	m S TFA
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.	•	ug/L «			
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.			0461	μg/2 (Δ) 60(Ω)	0023
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.		13.81	0.431	S 0.677	~ 0.023 ~ 0.02≇
15.11. + 22.11. 15.12. + 22.12. 10.29		15.19	W 2015	00734	0.020
15.11. + 22.11. 15.12. + 22.12. 10.29		20075	0.389	20,996	\$ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
15.11. + 22.11. 15.12. + 22.12. 08.04. + 15.04. 08.04. + 20.04		19.04	0.272	2 0.719 C	/ \$\int_{\infty} \int_{\infty} 0.014
15.11. + 22.11. 15.12. + 22.12. 15.12. + 22.12. 15.12. + 22.12.		@.O /12/k/ n	© \$\tilde{\pi}229 \@	0.430	0.011
15.11. + 22.11. 15.12. + 22.12. 10.29			®.157 ∜	® 183	0.008
15.11. + 22.11. 15.12. + 22.12. 10.29	15.08. + 22.08.	5,894	<i></i> √ 0.197√	3 0.254 €	0.010
15.11. + 22.11. 15.12. + 22.12. 15.12. + 22.12. 15.12. + 22.12.	15.09. + 22.09.	, P.137	0,341	0.347	0.017
$15.12. + 22.12. \qquad \begin{array}{ c c c c c c c c c c c c c c c c c c c$	15.10. + 22.10.	° ₹ 6.777 ° 2	2 0. 557 \$	0.330	0.028
15.12. + 22.12.	15.11. + 22.11.	5.414	0.317	© .263 g	0.016
08.04. + 15.04. 22.04. + 29.04 08.10. + 15.10 20.35 0.0383 0.0799 0.00 08.10. + 15.10 0.0488 0.0293 0.00 22.10. + 29200 0.00 0.0488 0.0366 0.00	15.12. + 22.12.	10 10×29 0	\$\tag{\tag{\tag{\tag{\tag{\tag{\tag{	©0.548	0.027
08.04. + 15.04.					0.010
22.10. + 29.04.0	08.04. + 15.04.	20.35	0.383	0.372	0.019
22.10. + 2920. 9.547 A	02 10 + 15 10		0.32	0.799	0.016
	22 10 + 29%	9.547 A	0.400	0.293	0.024
				Ÿ	



Table 9.2.5- 25: PEC_{sw} (50^{th} 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		Let	tuce	
Mitigation (end-of-pipe reduction)	0.	0/0	95	(0)
Species/	Fluopyram	TFA	Fluopyram	TFA
Application dates	μg/L	μg/L	µg/L	μg/V ζ
15.01. + 22.01.	21.85	0.743	Q1.092	29037 W
15.02. + 22.02.	21.95	0,460	[° 1.097	0.030 0.030 0.026
15.03. + 22.03.	29.74	0.602	1.486	0.030
15.04. + 22.04	41.02	®0.520 €	2049 Q	0,026
15.05. + 22.05.	36.08	0.435	× 1.799, × ×] \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
15.06 + 22.06.	18.45	0.435 0.435 0.267	0.922	>0.019 ^{√√}
15.07. + 22.07.	13.30	O' _ \$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0.922	(0.0 <u>1</u> 14
15.08. + 22.08.	14.52	0.281V	0.724	
15.09. + 22.09.	21.46	0.504	1.0730	0.042
15.10. + 22.10.	19.92	°√ 0 3 840 √	O 0.998 S	₩ 0.04 2
15.11. + 22.11.	12.3 Q	Ø.458	0612	0.023
15.12. + 22.12.	1800	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	© 29.933 D	0.047
08.04. + 15.04.	Q41.79	\$ \$\tag{\$15}	2.082	0.026
22.04. + 29.04.	43.59	® .531 √	2,178 °	0.027
08.10. + 15.10.	29.17	_√ 0.7 3 5. ✓	√ ×1.058 ©	0.037
22.10. + 29.10.	Q Q.12	0,895	J\$ 1.106	0.045

Table 9.2.5- 26 gives an overview of the CEM PEC_{sw} results for handing of filter cleaning water and mitigation options for Floopyran application dates in April for TFA application dates in October are leading to the maximum PEC_{sw}

Table 9.2.5 26: Maximum PCC_{sw} (50) perc of 7 annual peak concentrations) of fluopyram, 2 × 200 g/ba in lettere in greenhouse; soil less contivation

Crop/		Lett	uce	_
Crop/ Species/ Scenario	A S Bluop	extram	TF	·A
	Application/dates	μg/ I	Application dates	μg/L
No reuse of filter	Ŷ5.04;⊕22.04;¥	\$ 20 .05	15.10. + 22.10.	0.557
cleaning water; 0%				
mitigation				
No reuse of filter &	\$\$\04.\#@2.04.\	0.996	15.10. + 22.10.	0.028
clearling water; 95%		O		
mitigation	. Y Q	~		
With reuse of Miter 4	22.04. + 29.04.	43.59	22.10. + 29.10.	0.895
mitigation 🗸				
With recise of filter	22 (2. + 29.04.	2.178	22.10. + 29.10.	0.045
cleaning water 95%				
mitigation				



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 or 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

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.

Estimation of concentrations for other routes of exposure **CP 9.4**

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