European Commission

Draft Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

ISOFLUCYPRAM

Volume 3 – B.8 (PPP) – Isoflucypram EC 50

Rapporteur Member State : United Kingdom
Co-Rapporteur Member State : France

Version History

When	What
March 2019	Initial DAR

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B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Isoflucypram (CAS-No. 1255734-28-1) is a new fungicidal active substance developed by Bayer. This draft assessment report product assessment (DAR CP) evaluates the submission for regulatory approval of Isoflucypram in Europe under Regulation (EC) No 1107/2009. Isoflucypram is a novel broad spectrum fungicide of the chemical class of N-cyclopropyl-N-benzyl-pyrazole-carboxamides with application to cereal crops (wheat, triticale, rye, barley and oats) evaluated as part of this submission. Isoflucypram is an SDH inhibitor fungicide the application scope of isoflucypram-containing products on cereals with only one foliar spray at a maximum of 75 g a.s./ha at BBCH 39-69.

Throughout the development of isoflucypram the following synonyms may have been used and also referred to in individual study reports: Bayer Code: BCS-CN88460, BCS-CN88460-a.s., ´460 and the Bayer-internal short Code: ISY. All chemical substances described by either of these codes refer to the same chemical name and structural formula. A full list of common names is provided in table B.8.3 in the CA document, for the evaluation the Bayer common name Isoflucypram and code BCS-CN88460 are used. For the metabolites codes M12 are used for BCS-CN88460-carboxylic acid, M10 for BCS-CN88460-lactic acid and M11 *for* BCS-CN88460-desmethyl-carboxylic acid are used unless both name and code are presented. Structural formula are presented in table B.8-1 for isoflucypram and its main metabolite M12. Metabolite M10 was noted to be increasing at the end of some studies in soil but never exceeded 5% AR and hence did not trigger inclusion in risk assessment. In addition, DT50 values and formation fractions could not be calculated for metabolite M10. PECsoil values have been calculated, however insufficient endpoints were available to perform a groundwater assessment.

The models and version numbers used by the UK RMS are listed in table B.8-2, revised calculations were required to be performed by the UK RMS as the endpoints proposed by the applicant were different to those selected by the UK RMS in the relevant CA document to this assessment. The GAP table submitted by the applicant for assessment is listed in table B.8-3.

Table B.8.1: Structural formula of the main compounds investigated.

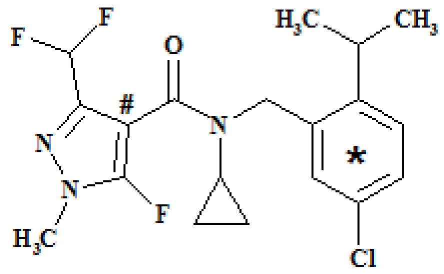
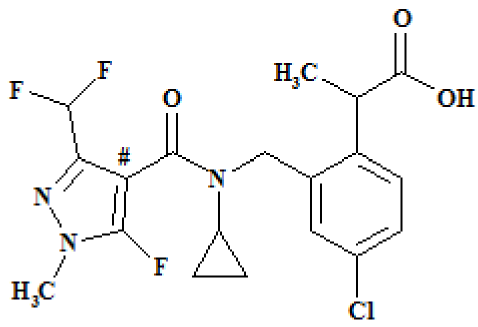
Structural formula of isoflucypram: *: [14]C-labeling position of the **phenyl-label** (short form used in this summary) = [chlorophenyl-UL-[14]C]isoflucypram #: [14]C-labeling position of the **pyrazole-label** (short form used in this summary) = [pyrazole-4-[14]C]isoflucypram	
Structural formula of M12 *(*BCS-CN88460-carboxylic acid*)*: #: [14]C-labeling position of the **pyrazolyl-labelled** BCS-CN88460-carboxylic acid (short form used in this summary) = [pyrazole-4-[14]C]BCS-CN88460-carboxylic acid	

Table B-2: Models used in the calculation of PECs for Isoflucypram EC50

Assessment / model	Model version
FOCUS surface water STEP 1 and 2	v. 3.2
FOCUS surface water STEP 3 SWASH	v. 5.3
FOCUS surface water STEP 3 TOXWA	v 4..4.3
FOCUS surface water STEP 3 PRZM	v 4.3.1
FOCUS surface water STEP 3 MACRO	v 5.5.4
FOCUS STEP 4 SWAN	v. 4.0.1
FOCUS ground water modelling PEARL	v. 4.4.4
FOCUS ground water modelling PELMO	v. 5.5.3
ESCAPE	v. 2

Table B-3. Gap table submitted by the applicant for assessment

Crop and/or situation	Member State or Country	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
				Type/ Conc. of a.s.	Rate L/ha	Method / Kind	Timing/ Growth stage of crop & season	Number min max	Interval between applic. min (days)	kg a.s./hL min max	Water L/ha min max	kg a.s./ha min max		
(a)		(b)	(c)	(d-f)		(g-h)	(j)	(k)					(l)	(m)
wheat	EU	F	*Mycosphaerella graminicola, Puccinia recondita, Puccinia striiformis, Pyrenophora tritici-repentis*	EC50	1.5	Foliar spray	BBCH 30-69	1	-	-	100-400	0.075	*	* A Pre-Harvest-Interval for use in wheat (including durum wheat and spelt), rye and triticale is not applicable; the timing is defined by the growth stage at application.
rye	EU	F	*Puccinia recondita, Rhynchosporium secalis*	EC50	1.5	Foliar spray	BBCH 30-69	1	-	-	100-400	0.075	*	
triticale	EU	F	*Mycosphaerella graminicola, Puccinia recondita, Puccinia striiformis, Pyrenophora tritici-repentis*	EC50	1.5	Foliar spray	BBCH 30-69	1	-	-	100-400	0.075	*	
barley	EU	F	*Rhynchosporium secalis, Pyrenophora teres, Puccinia hordei, Ramularia collo-cygni*	EC50	1.5	Foliar spray	BBCH 30-61	1	-	-	100-400	0.075	*	* A Pre-Harvest-Interval for use in barley and oats is not applicable; the timing is defined by the growth stage at application.
oats	EU	F	*Puccinia coronata, Pyrenophora avenae*	EC50	1.5	Foliar spray	BBCH 30-61	1	-	-	100-400	0.075	*	

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

The guidance documents used by the UK RMS to perform the calculations that underpin the risk assessment are listed below.

The guidance used within this new substance evaluation:

FOCUS (2006) Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, June 2006

FOCUS (2001). FOCUS Surface Water scenarios in the EU Evaluation process under 91/414/EEC. Report of the FOCUS working group on Surface water Scenarios, EC Document Reference Sanco/4802/2001 rev 2 final (May 03).

FOCUS (2007). Landscape and Mitigation Factors in Aquatic risk assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS working group on Landscape and Mitigation Factors in Ecological risk assessment, EC Document Reference Sanco/10422/2005 v2.0.

FOCUS (2011). Generic guidance for Tier 1 FOCUS groundwater scenarios. Version 2.0, January 2011

FOCUS (2015). Generic guidance FOCUS surface water scenarios. Version 1.4,

EFSA DegT50 guidance (EFSA journal 2014; 12(5):3662))

B.8.1. FATE AND BEHAVIOUR IN SOIL

B.8.1.1. **Route and rate of degradation in soil**

For full details of the assessment of degradation in soil see the associated CA.B.8 document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.1.2. **Mobility in soil**

For full details of the assessment of degradation in soil see the associated CA.B.8 document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_S)

For the calculation of PECsoil non-normalised DT50 values assessed in the CA document of this assessment are listed in table B.8.2.1-2. Worst case soil degradation values resulting from the field dissipation studies are listed for Isoflucypram and its metabolite M12. Metabolite M10 did not exceed 5% of AR in any laboratory assessment and was not a metabolite that was assessed in the field assessment.

For isoflucypram, biphasic kinetics were considered to be worst case by the RMS and the model ESCAPE V2 was used by the RMS for the calculation of PEC soil. PECsoil calculations are provided as a worst case concentration in soil using the longest DT50 calculated in soil and the worst case accumulation concentration using the worst case DT90 value calculated in soil. The GAP calculated is listed in table B.8.2.1-1. Due to the potentially wide window of application the worst case early applications has been simulated as this attracts the lowest amount of crop interception for the GAP. All assessments have been made assuming a 5 cm incorporation depth for annual applications; this is to reflect an assessment of potential accumulation in soil under minimum/shallow tillage practice. This value is considered to be conservative compared to an assumption of 20cm tillage depth.

Table B.8.2.1-1: GAP table assessed for PECsoil

Individual Crop	FOCUS crop used for Interception	Application				Amount reaching the soil per application	Application Depth (cm)	Soil density kg/L
		Rate per Season [g a.s./ha]	Interval [days]	Plant Interception [%]	BBCH Stage	[g a.s./ha]		
Cereals	Cereals	1 × 75	-	80	30 - 69	1 × 15	5*	1.5

* For accumulation this is considered to be worst case for minimum and shallow tillage systems

Table B.8.2.1-2: Endpoints used in the assessment of PECsoil

Endpoint	**Value used for modelling concentrations in soil after one year.**	**Value used for modelling accumulations in soil**
Isoflucypram		
Molecular weight [g/mol]	399.85	
Model	DFOP	DFOP
DT_{50} soil [days] (maximum field., not-normalised)	177	72.4
DT_{90} soil [days] (maximum field., not-normalised)	1810	3090
K1 *(DT_{50})	0.0078 (88.9)	0.0210 (33.1)
K2 *(DT_{50})	0.0007 (1020)	0.0004 (1810)
g	0.610	0.627
M12		
Molecular weight [g/mol]	429.8	
DT_{50} soil [days] (maximum lab., not-normalised)	714 (SFO)	
formation fraction (worst case non normalised field SFO)	0.071	

* K values rounded which accounts for difference between k and calculated DT50.

B.8.2.2: PECsoil values

Table B.8.2.2-1: PECsoil values Cereals Early, Isoflucypram. Worst case concentration is soil.

Time (Days)	PECactual (mg/kg)	PECtwa (mg/kg)
PECmax	0.0200	-
1	0.0199	0.0200
2	0.0199	0.0199
4	0.0198	0.0199
7	0.0196	0.0198
14	0.0193	0.0197
21	0.0190	0.0195
28	0.0186	0.0193
42	0.0180	0.0190
50	0.0177	0.0188
100	0.0158	0.0177
Accumulation *	0.0616 after 21 years, steady state 0.0416	-

* Calculation performed with the worst case DT90 value parameters.

Table B.8.2.2-2: PECsoil values Cereals Early, M12. Worst case concentration is soil.

Time (Days)	PECactual (mg/kg)	PECtwa (mg/kg)
PECmax	0.0012	-
1	0.0012	0.0012
2	0.0012	0.0012
4	0.0012	0.0012
7	0.0012	0.0012
14	0.0012	0.0012
21	0.0012	0.0012

28	0.0012	0.0012
42	0.0011	0.0012
50	0.0011	0.0012
100	0.0011	0.0012
Accumulation *	0.0055 after 14 years	-

* Calculation performed with the worst case DT90 value parameters.

B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC_{GW})

Biphasic kinetics were derived in the CA document of this assessment, with biphasic degradation endpoints from field dissipation studies selected using the EFSA DegT50 guidance (2014) (DFOP (n=5) and HS (n=1)). Geomean fast phase (n=6) and geomean slow phase (n=6) DT50 values were derived, as well as an arithmetic mean g value. Substance endpoints used by the RMS are listed in table B.8.3-2 and GAP details are listed in table B.8.3-1. The applicant proposed application dates which are listed in table B.8.3-3; these dates are considered reasonable by the UK RMS, UK RMS used the senescence dates and emergence dates from the models as a guide to for the consideration of the application window. The E.U. agreed models PEARL, PELMO and MACRO were used. It is noted by UKRMS that metabolite M10 does not formally trigger groundwater assessment according to E.U. guidance on assessment of metabolites in groundwater. However it is noted that EFSA have stated that identified metabolites increasing at the end of a soil route of degradation study but at less than 5% A.R. must be addressed for potential relevance if they were predicted to occur in shallow groundwater at greater than 0.1µg/L. With a maximum formation of 3.9% of A.R. M10 was increasing at the termination of the study and may need further consideration as noted above. No endpoints are available to perform groundwater exposure modelling and UKRMS suggests this be discussed at E.U. peer review as to whether a request for further information to the applicant, such that a groundwater assessment can be performed, is justified.

For the calculation of PECgw the RMS has taken a 2 tier approach. At the first tier, two separate simulations were performed for each timing option (early cereals or late cereals), one using the fast phase of DFOP as the degradation rate for the parent and one using the slow phase of DFOP for the parent. Both simulations used a TSCF value of 0 for the parent. At the second tier, the TSCF value for the parent was changed to 0.1 following a calculation of TSCF using the Briggs equation. To assess the viability of this method as a refinement, an initial calculation was performed on the worst case results from the tier 1 assessment. PEC results are presented in table B.8.3.1-9, but when compared to the results from table B.8.3.1-2, the addition of the PUF refinement for parent does not significantly refine the metabolite PECgw values. Further simulations were therefore not performed. Metabolite M12 was noted to be pH dependant for sorption only, worst case Koc and 1/n values were proposed by the applicant to address all soils. UK RMS agreed to this approach in order to derive a conservative assessment for the concentration of M12 in groundwater.

Table B.8.3-1: GAP table assessed for PECgw.

Individual Crop	FOCUS crop used for Interception	Application				Amount reaching the soil per application	Application Depth (cm)
		Rate per Season [g a.s./ha]	Interval [days]	Plant Interception [%]	BBCH Stage	[g a.s./ha]	
Cereals, early	Cereals	1 × 75	-	80	30 - 39	1 × 15	0
Cereals, late	Cereals	1 × 75	-	90	40 - 69	1 × 7.5	0

Table B.8.3-2: Endpoints used in the PEC groundwater assessment.

Parameter	**Unit**	**Isoflucypram**	**(M12)**
Molar mass	(g/mol)	399.85	429.8
Water solubility 20°C	(mg/L)	1.8	10100
Volatility 20°C	pa	1.2 E-7	2.610-13
Koc/ kom	(mL/g)	1346.6/ 781.1	37.1/ 21.5
1/n		0.907	0.942
Degradation			
Soil (fast/ slow)	(days)	11.1/ 324.3	105.5
Transformation rate soil		0.0060/0.00025	-
Transformation rate Co2		0.0564/0.00193	-
Soil g value (Arethmetric mean, n=5)		0.5055	-
Max occurrence			
Soil	(%)	100	9.6
Formation fraction			
Soil		-	0.00192
Conversion fraction Macro*		0.10	0.103
TSCF tier 1			0
TSCF tier 2			0

*MM metabolite/MM parent x formation fraction.

Table B.8.3.2-3: Application dates used in the groundwater assessment.

Individual crop	**Winter cereals, early**	**Winter cereals, late**	**Spring cereals, early**	**Spring cereals, late**
Repeat interval for app. events	Every Year	Every Year	Every Year	Every Year
Application technique	Spray	Spray	Spray	Spray
Absolute / Relative to	Absolute	Absolute	Absolute	Absolute
Scenario	1st app. date (Julian day)	1st app. date (Julian day)	1st app. date (Julian day)	1st app. date (Julian day)
Chateaudun	21 Apr (111) -	14 Jun (165) -	10 Apr (100) -	22 Jun (173) -
Hamburg	19 Apr (109) -	22 Jun (173) -	28 Apr (118) -	28 Jun (179) -
Jokioinen	25 May (145) -	10 Jul (191) -	05 Jun (156) -	17 Jul (198) -
Kremsmuenster	19 Apr (109) -	22 Jun (173) -	28 Apr (118) -	28 Jun (179) -
Okehampton	15 Apr (105) -	07 Jun (158) -	22 Apr (112) -	18 Jun (169) -
Piacenza	10 Apr (100) -	25 May (145) -	- - -	- - -
Porto	30 Mar (89) -	24 May (144) -	16 Apr (106) -	22 Jun (173) -
Sevilla	06 Jan (6) -	28 Mar (87) -	- - -	- - -
Thiva	02 Mar (61) -	27 Apr (117) -	- - -	- - -

<u>First tier PEC groundwater assessment.</u>

For a first tier assessment, PEC values were calculated by the RMS for 100% of the parent degrading via either the fast phase DT50 or the slow phase DT50, principally to determine the influence on the PECgw values for metabolite M12. The resulting PECs were then assessed to check the merits of distributing the soil loadings via the g value in to either the fast of the slow phase as a higher tier assessment. As can be seen in the tables below, for metabolite M12 the use of fast phase DT50 or slow phase DT50 for the parent results in no change to the regulatory outcome for individual scenarios, i.e. use of fast phase DT50 or slow phase DT50 for the parent makes no difference to whether an individual scenario predicts 80th percentile annual average concentrations of M12 above or below 0.1 µg/l at 1m depth. Therefore a full implementation of biphasic kinetics for isoflucypram will not alter the regulatory outcome of the assessment for metabolite M12. To assess other refinements a second tier groundwater assessment has been performed, details are included in sections further below.

Table B.8.3.1-1: PEC groundwater for isoflucypram and metabolite M12; fast phase DT50 for parent. Winter cereals, early applications.

Crop	**Scenario**	**80th percentile PEC_{gw} at 1 m soil depth (µg/L)**			
		Isoflucypram (fast DT50)		**M12**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Winter cereals, early (1x 15g/ha)	Chateaudun	<0.001	<0.001	0.212	0.096
	Hamburg	<0.001	<0.001	0.352	0.179
	Jokioinen	<0.001	<0.001	0.336	0.160
	Kremsmuenster	<0.001	<0.001	0.247	0.133
	Okehampton	<0.001	<0.001	0.239	0.123
	Piacenza	<0.001	<0.001	0.178	0.102
	Porto	<0.001	<0.001	0.157	0.082
	Sevilla	<0.001	<0.001	0.026	0.030
	Thiva	<0.001	<0.001	0.194	0.055
		MACRO		**MACRO**	
Winter cereals, early	Chateaudun	<0.001		0.0839	

Table B.8.3.1-2: PEC groundwater for isoflucypram and metabolite M12; slow phase DT50 for parent. Winter cereals, early applications

Crop	**Scenario**	**80th percentile PEC_{gw} at 1 m soil depth (µg/L)**			
		Isoflucypram		**M12**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Winter cereals, early (1x 15g/ha)	Chateaudun	<0.001	<0.001	0.247	0.135
	Hamburg	<0.001	<0.001	0.392	0.237
	Jokioinen	<0.001	<0.001	0.311	0.185
	Kremsmuenster	<0.001	<0.001	0.271	0.180
	Okehampton	<0.001	<0.001	0.270	0.171
	Piacenza	<0.001	<0.001	0.219	0.167
	Porto	<0.001	<0.001	0.191	0.125
	Sevilla	<0.001	<0.001	0.037	0.052
	Thiva	<0.001	<0.001	0.282	0.108
		MACRO		**MACRO**	
Winter cereals, early	Chateaudun	<0.001		0.107	

Table B.8.3.1-3: PEC groundwater for isoflucypram and metabolite M12; fast phase DT50 for parent.. Spring cereals, early applications,.

Crop	**Scenario**	**80th percentile PEC_{gw} at 1 m soil depth (µg/L)**			
		Isoflucypram (fast DT50)		**M12**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Spring cereals, early (1x 15g/ha)	Chateaudun Hamburg Jokioinen Kremsmuenster Okehampton Porto	<0.001 <0.001 <0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001 <0.001 <0.001 <0.001	0.190 0.444 0.288 0.273 0.254 0.168	0.078 0.169 0.136 0.130 0.117 0.075
		MACRO		**MACRO**	
Winter cereals, early	Chateaudun	<0.001		0.075	

Table B.8.3.1-4: PEC groundwater for isoflucypram and metabolite M12; slow phase DT50 for parent. Spring cereals, early applications.

Crop	**Scenario**	**80th percentile PEC_{gw} at 1 m soil depth (µg/L)**			
		Isoflucypram		**M12**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Spring cereals, early (1x 15g/ha)	Chateaudun Hamburg Jokioinen Kremsmuenster Okehampton Porto	<0.001 <0.001 <0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001 <0.001 <0.001 <0.001	0.222 0.462 0.273 0.289 0.185 0.107	0.111 0.224 0.149 0.167 0.155 0.113
		MACRO		**MACRO**	
Winter cereals, early	Chateaudun	<0.001			

Table B.8.3.1-5: PEC groundwater for isoflucypram and metabolite M12; fast phase DT50 for parent.. Winter cereals, late applications.

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)			
		Isoflucypram(fast DT50)		M12	
		PEARL	PELMO	PEARL	PELMO
Winter cereals, late (1x 7.5 g/ha)	Chateaudun	<0.001	<0.001	0.103	0.049
	Hamburg	<0.001	<0.001	0.184	0.093
	Jokioinen	<0.001	<0.001	0.163	0.080
	Kremsmuenster	<0.001	<0.001	0.118	0.066
	Okehampton	<0.001	<0.001	0.120	0.061
	Piacenza	<0.001	<0.001	0.085	0.053
	Porto	<0.001	<0.001	0.083	0.044
	Sevilla	<0.001	<0.001	0.011	0.014
	Thiva	<0.001	<0.001	0.103	0.028
		MACRO		MACRO	
Winter cereals, early	Chateaudun	<0.001		0.044	

Table B.8.3.1-6: PEC groundwater for isoflucypram and metabolite M12; slow phase DT50 for parent.. Winter cereals, late applications.

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)			
		Isoflucypram		M12	
		PEARL	PELMO	PEARL	PELMO
Winter cereals, late (1x 7.5 g/ha)	Chateaudun	<0.001	<0.001	0.118	0.065
	Hamburg	<0.001	<0.001	0.189	0.115
	Jokioinen	<0.001	<0.001	0.148	0.088
	Kremsmuenster	<0.001	<0.001	0.131	0.087
	Okehampton	<0.001	<0.001	0.132	0.083
	Piacenza	<0.001	<0.001	0.106	0.080
	Porto	<0.001	<0.001	0.093	0.061
	Sevilla	<0.001	<0.001	0.016	0.024
	Thiva	<0.001	<0.001	0.137	0.052
		MACRO		MACRO	
Winter cereals, early	Chateaudun	<0.001			

Table B.8.3.1-7: PEC groundwater for isoflucypram and metabolite M12; fast phase DT50 for parent. Spring cereals, late applications,

Crop	**Scenario**	**80th percentile PEC_{gw} at 1 m soil depth (µg/L)**			
		Isoflucypram (fast DT50)		**M12**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Spring cereals, late (1x 7.5 g/ha)	Chateaudun Hamburg Jokioinen Kremsmuenster Okehampton Porto	<0.001 <0.001 <0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001 <0.001 <0.001 <0.001	0.097 0.231 0.146 0.134 0.124 0.081	0.041 0.087 0.069 0.063 0.059 0.043
		MACRO		**MACRO**	
Winter cereals, early	Chateaudun	<0.001		0.0404	

Table B.8.3.1-8: PEC groundwater for isoflucypram and metabolite M12; slow phase DT50 for parent. Spring cereals late applications

Crop	**Scenario**	**80th percentile PEC_{gw} at 1 m soil depth (µg/L)**			
		Isoflucypram		**M12**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Spring cereals, late (1x 7.5 g/ha)	Chateaudun Hamburg Jokioinen Kremsmuenster Okehampton Porto	<0.001 <0.001 <0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001 <0.001 <0.001 <0.001	0.107 0.222 0.131 0.139 0.137 0.090	0.053 0.109 0.072 0.081 0.075 0.056
		MACRO		**MACRO**	
Winter cereals, early	Chateaudun	<0.001			

<u>Higher tier groundwater assessment</u>

Since first tier PEC values in groundwater for metabolite M12 exceed the groundwater trigger of 0.1µg/L in a majority of scenarios using either the fast or slow phase of DFOP kinetics for isoflucypram, the next step of a full implementation of DFOP was considered by the RMS to be unlikely to alter the regulatory outcome of the assessment.

To refine the groundwater investigation further, altering the TSCF of isoflucypram to the value calculated using the Briggs equation accepted in the CA document was attempted by the UK RMS. The accepted value of 0.1 for isoflucypram was substituted and the worst case scenario assessed. From table B.8.3.1-9 it can clearly be seen that minimal or no effect on the metabolite concentration is observed when altering the parent TSCF value. Further investigation was considered not to be required as further modelling will not affect the regulatory outcome of the assessment. A summary table is provided at table B.8.3.1-10 to outline which scenarios pass the risk assessment and the level of exceedance of metabolite M12.

B.8.3.1-9: PEC groundwater for isoflucypram and metabolite M12; slow phase. Winter cereals, early applications using a parent TSCF value of 0.1.

Crop	**Scenario**	**80th percentile PEC_{gw} at 1 m soil depth (µg/L)**			
		Isoflucypram		**M12**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Winter cereals, early (1x 15g/ha)	Chateaudun	<0.001	<0.001	0.246	0.134
	Hamburg	<0.001	<0.001	0.391	0.234
	Jokioinen	<0.001	<0.001	0.311	0.184
	Kremsmuenster	<0.001	<0.001	0.271	0.179
	Okehampton	<0.001	<0.001	0.270	0.169
	Piacenza	<0.001	<0.001	0.219	0.165
	Porto	<0.001	<0.001	0.191	0.123
	Sevilla	<0.001	<0.001	0.036	0.051
	Thiva	<0.001	<0.001	0.281	0.106
		MACRO		**MACRO**	
Winter cereals, early	Chateaudun	<0.001			

Summary of the PECground water assessment.

PECgroundwater assessments using either DFOP slow phase or fast phase DT50 for the active substance demonstrate that all FOCUS scenarios predict 80th percentile annual average concentrations <0.001 µg/l at all scenarios for the active substance at the first tier. Metabolite M12 was predicted to have concentrations >0.1 µg/l at a majority of simulated scenarios. A full implementation of DFOP kinetics for isoflucypram would not change the regulatory outcome for metabolite M12 as it would not have changed the number of scenarios where M12 would be predicted to occur at <0.1 µg/l. A higher tier assessment using the calculated TSCF value for the parent was attempted. This did not reduce the PEC values of M12 significantly compared to tier 1, therefore the first tier assessment is relied upon. At the first tier some scenarios predicted concentrations of M12 <0.1 µg/l, and these are detailed in table B.8.3.1-10.

Table B.8.3.1-10: Summary table of FOCUSgw assessment.

Crop	timing	Scenarios passing	Maximum concentration Isoflucypram µg/L	Maximum concentration M12 µg/L passing	Maximum concentration M12 µg/L
Winter cereals	Early	Sevilla	<0.001	0.037	0.392
	Late	Porto, Sevilla	<0.001	0.093	0.189
Spring cereals	Early	-	<0.001	-	0.462
	Late	Porto	<0.001	0.090	0.232

B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

B.8.4.1. **Aerobic mineralisation in surface water**

For full details of the assessment of degradation in soil see the associated CA document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.4.2. **Water/sediment study**

For full details of the assessment of degradation in soil see the associated CA document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.4.3. **Irradiated water/sediment study**

For full details of the assessment of degradation in soil see the associated CA document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC_{SW}, PEC_{SD})

Endpoints presented by the RMS in the CA document with regards to surface water were different to those proposed by the applicant. UK RMS has therefore remodelled the PECsw and PECsed assessment for the applicant's proposed application and scenarios as detailed in table B.8.5.1.1. Endpoints used by the UK RMS are listed in table B.8.5.1.2 for steps 1 and 2 and B.8.5.1.3 for steps 3 and 4. UK RMS has assessed the supplied application dates for Steps 3 and 4 and accepts the proposed dates with one exception. UK RMS noted for winter cereals for D3 that the start date for early applications proposed by the applicant was slightly later than the start date for late applications; no justification was provided for this by the applicant as to why the early application would be at a slightly later time than the later applications. UK RMS has altered the date to an earlier time which is consdered to be more appropriate) for the surface water assessment at steps 3 and 4.

According to FOCUS Degradation Kinetics v 1.1, chapter 10 on pages 193-194 and FOCUSsw generic guidance v 1.4, page 212 - 213 (particularly the footnote on p 213), at Step 3, substances with Koc values between 100 and 2000 ml/g should be modelled with the water/sediment whole system DT50 value in water and default value of 1000 days in sediment in one simulation and with the default value of 1000 days in water and the water sediment whole system DT50 in sediment in a separate simulation. UK RMS has performed a Step 3 assesment for the parent according to this guidance. The worst case assessment from this approach will be taken to step 4 as a conservative assessment of the PECsw of isoflucypram and its metabolite M12.

The RAC is sediment was confirmed by eco-toxicology to be 10,000 µg/kg. Therefore assessment using the highest and lowest Koc for M12 was not considered to be necessary to assess the pH dependant nature. The use of the higher Koc value is unliley to produce PECsed values that would fail the assessment. The use of the worst case value will be conservative with regards to the surface water assessment.

Table B.8.5.1.1: GAP table and scenarios assessed

Crop	BBCH stage	Rate [g a.s./ha]	Interval [days]	FOCUS crop (crop group)	Season	Crop cover
Cereals	30-69	1 × 75	-	Winter cereals	Spring (Mar. - May)	Average crop cover
		1 × 75		Winter cereals	Summer (Jun. – Sep.)	Full canopy
		1 × 75		Spring cereals	Spring (Mar. - May)	Average crop cover
		1 × 75		Spring cereals	Summer (Jun. – Sep.)	Full canopy

Table B.8.5.1.2: Endpoints used at step 1 and 2

Parameter	Unit	Isoflucypram	BCS-CN88460-carboxylic acid (M12)
Molar mass	(g/mol)	399.85	429.8
Water solubility	(mg/L)	1.8	10100
Koc	(mL/g)	1346.6	37.1
Degradation			
Soil	(days)	324.3	105.5
Total system	(days)	388	1000
Water	(days)	388	1000
Sediment	(days)	388	1000
Max occurrence			
Water / sediment	(%)	100	6.6
Soil	(%)	100	9.6

Table B.8.5.1.3: Endpoints used at step 3 and 4

Parameter	Unit	Isoflucypram	BCS-CN88460-carboxylic acid (M12)
Molar mass	(g/mol)	399.85	429.8
Koc	(mL/g)	1346.6	37.1
Degradation			
Soil	(days)	324.3	105.5
		388/1000	1000
Water	(days)	1000/388	1000
Sediment	(days)		
Formation fraction		-	0.240
Water / sediment	(%)	-	0.192
Soil	(%)	1.8	10100
Water soluibility 20°C	mg/L	1.2 E-7	2.610-13
Volatility 20°C	pa		

Table B.8.5.1.4: Application dates proposed by the applicant and accepted by UKRMS

Parameter	**Winter cereals, early**		**Winter cereals, late**		**Spring cereals, early**		**Spring cereals, late**	
PAT start date rel./absolute Appl. method (appl. type) No of appl. PAT window range Appl. interval	Absolute ground spray (CAM 2) 1 30 -		Absolute ground spray (CAM 2) 1 30 -		Absolute ground spray (CAM 2) 1 30 -		Absolute ground spray (CAM 2) 1 30 -	
Drainage scenarios	**PAT start/end date (Julian day)**	**Appli-cation date**	**PAT start/end date (Julian day)**	**Appli-cation date**	**PAT start/end date (Julian day)**	**Appli-cation date**	**PAT start/end date (Julian day)**	**Appli-cation date**
D1 Ditch/Stream	20-Apr/20-May (110/140)	25-Apr	12-Jun/12-Jul (163/193)	17-Jun	27-May/26-Jun (147/177)	17-Jun	18-Jun/18-Jul (169/199)	24-Jun
D2 Ditch/Stream	23-May/22-Jun (143/173)	23-May	11-Jun/11-Jul (162/192)	13-Jun	-	-	-	-
D3 Ditch	02-May/01-Jun (122/152)	04-May	01-Jul/31-Jul (182/212)	08-Jul	28-Apr/28-May (118/148)	04-May	29-May/28-Jun (149/179)	28-May
D4 Pond/Stream	21-Apr/21-May (111/141)	21-Apr	09-Jun/09-Jul (160/190)	04-Jul	18-May/17-Jun (138/168)	30-May	09-Jun/09-Jul (160/190)	04-Jul
D5 Pond/Stream	15-Mar/14-Apr (74/104)	08-Apr	03-May/02-Jun (123/153)	11-May	09-Apr/09-May (99/129)	14-Apr	05-May/04-Jun (125/155)	11-May
D6 Ditch	02-Mar/01-Apr (61/91)	05-Mar	28-Mar/27-Apr (87/117)	09-Apr	-	-	-	-
R1 Pond/Stream	20-Apr/20-May (110/140)	26-Apr	26-May/25-Jun (146/176)	13-Jun	-	-	-	-
R3 Stream	10-Apr/10-May (100/130)	11-Apr	25-Apr/25-May (115/145)	25-Apr	-	-	-	-
R4 Stream	15-Mar/14-Apr (74/104)	21-Mar	03-May/02-Jun (123/153)	04-May	09-Apr/09-May (99/129)	04-May	05-May/04-Jun (125/155)	05-May

Table B.8.5.2-1: Isoflucypram step 1 and step 2 tables

					Mar-May		Jun-Sep	
			Step 1 (µg/L)		Step 2 (µg/L)		Step 2 (µg/L)	
			PECsw	PECsed	PECsw	PECsed	PECsw	PECsed
Spring cereals	Average crop cover	N Europe	9.63	123.53	1.73	22.36	1.73	22.36
		S Europe	9.63	123.53	3.15	41.43	2.44	31.90
	Full crop cover	N Europe	9.63	123.53	0.84	10.44	0.84	10.44
		S Europe	9.63	123.53	1.38	17.60	1.11	14.02
Winter cereals	Average crop cover	N Europe	9.63	123.53	1.73	22.36	1.73	22.36
		S Europe	9.63	123.53	3.15	41.43	2.44	31.90
	Full crop cover	N Europe	9.63	123.53	0.84	10.44	0.84	10.44
		S Europe	9.63	123.53	1.38	17.60	1.11	14.02

Table B.8.5.2-2: Metabolite M12 step 1 and 2 tables

					Mar-May		Jun-Sep	
			Step 1(µg/L)		Step 2 (µg/L)		Step 2 (µg/L)	
			PECsw	PECsed	PECsw	PECsed	PECsw	PECsed
Spring cereals	Average crop cover	N Europe	4.20	1.56	0.70	0.26	0.70	0.26
		S Europe	4.20	1.56	1.35	0.50	1.02	0.38
	Full crop cover	N Europe	4.20	1.56	0.29	0.11	0.29	0.11
		S Europe	4.20	1.56	0.54	0.20	0.41	0.15
Winter cereals	Average crop cover	N Europe	4.20	1.56	0.70	0.26	0.70	0.26
		S Europe	4.20	1.56	1.35	0.50	1.02	0.38
	Full crop cover	N Europe	4.20	1.56	0.29	0.11	0.29	0.11
		S Europe	4.20	1.56	0.54	0.20	0.41	0.15

Table B.8.5.2-3: Isoflucypram winter cereals, Early application. Step 3 results DT_{50} water 1000 days.

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**	**Dominant entry route**
Step 3	Winter cereals early applications DT_{50} water 1000 days, DT_{50} sediment 388 days			
D1	Ditch	1.387	16.87	Drainage
D1	Stream	0.869	9.470	Drainage
D2	Ditch	1.369	11.95	Drainage
D2	Stream	0.8551	7.001	Drainage
D3	Ditch	0.4745	0.3012	Drift
D4	Pond	0.1005	0.9378	Drainage
D4	Stream	0.3652	0.3308	Drift
D5	Pond	0.1182	1.287	Drainage
D5	Stream	0.3798	0.2973	Drift
D6	Ditch	0.7443	0.8782	Drainage
R1	Pond	0.0425	0.5353	Runoff
R1	Stream	0.3124	0.3745	Drift
R3	Stream	0.4415	0.6982	Drift
R4	Stream	0.4364	0.6228	Runoff

Table B.8.5.2-4: Isoflucypram winter cereals, Late application. Step 3 results DT_{50} water 1000 days.

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**	**Dominant entry route**
Step 3	Winter cereals late applications DT_{50} water 1000 days, DT_{50} sediment 388 days			
D1	Ditch	0.6537	8.425	Drift
D1	Stream	0.4216	4.461	Drift
D2	Ditch	0.8686	0.8595	Drainage
D2	Stream	0.5859	5.165	Drift
D3	Ditch	0.4755	0.3667	Drift
D4	Pond	0.0529	0.5021	Drainage
D4	Stream	0.4103	0.1803	Drift
D5	Pond	0.0600	0.6930	Drainage
D5	Stream	0.4426	0.1541	Drift
D6	Ditch	0.4768	0.6666	Drift
R1	Pond	0.0531	0.6437	Runoff
R1	Stream	0.3133	0.8635	Drift
R3	Stream	0.4415	0.2616	Drift
R4	Stream	0.3921	0.8709	Runoff

Table B.8.5.2-5: Isoflucypram Spring cereals, Early application. Step 3 results DT_{50} water 1000 days.

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**	**Dominant entry route**
Step 3	Spring cereals early applications DT_{50} water 1000 days, DT_{50} sediment 388 days			
D1	Ditch	1.181	16.72	Drainage
D1	Stream	0.7401	9.378	Drainage
D3	Ditch	0.4746	0.3053	Drift
D4	Pond	0.1224	1.240	Drainage
D4	Stream	0.3880	0.4085	Drift
D5	Pond	0.1113	1.234	Drainage
D5	Stream	0.3992	0.2732	Drift
R4	Stream	0.4179	0.9130	Runoff

Table B.8.5.2-6: Isoflucypram Spring cereals, Late application. Step 3 results DT_{50} water 1000 days.

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**	**Dominant entry route**
Step 3	Spring cereals Late applications DT_{50} water 1000 days, DT_{50} sediment 388 days			
D1	Ditch	0.6891	9.099	Drift
D1	Stream	0.4226	4.971	Drift
D3	Ditch	0.4750	0.3310	Drift
D4	Pond	0.0699	0.7047	Drainage
D4	Stream	0.4090	0.2344	Drift
D5	Pond	0.0635	0.7358	Drainage
D5	Stream	0.4142	0.1547	Drift
R4	Stream	0.4361	0.9502	Runoff

Table B.8.5.2-7: Isoflucypram winter cereals, Early application. Step 3 results DT_{50} water 388 days.

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**	**Dominant entry route**
Step 3	Winter cereals early applications DT_{50} water 388 days, DT_{50} sediment 1000 days			
D1	Ditch	1.388	17.87	Drainage
D1	Stream	0.8694	9.957	Drainage
D2	Ditch	1.369	12.79	Drainage
D2	Stream	0.8551	7.493	Drainage
D3	Ditch	0.4745	0.3013	Drift
D4	Pond	0.1002	0.9519	Drainage
D4	Stream	0.3652	0.3313	Drift
D5	Pond	0.1178	1.347	Drainage
D5	Stream	0.3798	0.3043	Drift
D6	Ditch	0.7444	0.9187	Drainage
R1	Pond	0.0421	0.5490	Runoff
R1	Stream	0.3124	0.3801	Drift
R3	Stream	0.4415	0.6985	Drift
R4	Stream	0.4367	0.6238	Runoff

Table B.8.5.2-8: Isoflucypram winter cereals, late application. Step 3 results DT_{50} water 388 days.

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**	**Dominant entry route**
Step 3	Winter cereals late applications DT_{50} water 388 days, DT_{50} sediment 1000 days			
D1	Ditch	0.6541	8.855	Drift
D1	Stream	0.4216	4.653	Drift
D2	Ditch	0.8686	9.077	Drainage
D2	Stream	0.5859	5.463	Drift
D3	Ditch	0.4745	0.3013	Drift
D4	Pond	0.0563	0.5044	Drainage
D4	Stream	0.4103	0.1810	Drift
D5	Pond	0.0600	0.6930	Drainage
D5	Stream	0.4426	0.1541	Drift
D6	Ditch	0.4768	0.6698	Drift
R1	Pond	0.0521	0.6473	Runoff
R1	Stream	0.3133	0.8641	Drift
R3	Stream	0.4415	0.2574	Drift
R4	Stream	0.3921	0.8717	Runoff

Table B.8.5.2-9: Isoflucypram Spring cereals, early application. Step 3 results DT_{50} water 388 days.

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**	**Dominant entry route**
Step 3	Spring cereals early applications DT_{50} water 388 days, DT_{50} sediment 1000 days			
D1	Ditch	1.181	17.50	Drainage
D1	Stream	0.7401	9.775	Drainage
D3	Ditch	0.4746	0.3054	Drift
D4	Pond	0.1220	1.246	Drainage
D4	Stream	0.3880	0.4095	Drift
D5	Pond	0.1107	1.266	Drainage
D5	Stream	0.3992	0.2779	Drift
R4	Stream	0.4178	0.9139	Runoff

Table B.8.5.2-10: Isoflucypram Spring cereals, late application. Step 3 results DT_{50} water 388 days.

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**	**Dominant entry route**
Step 3	Spring cereals late applications DT_{50} water 388 days, DT_{50} sediment 1000 days			
D1	Ditch	0.6894	9.547	Drift
D1	Stream	0.4226	5.183	Drift
D3	Ditch	0.4750	0.3311	Drift
D4	Pond	0.0696	0.7082	Drainage
D4	Stream	0.4090	0.2351	Drift
D5	Pond	0.0631	0.7551	Drainage
D5	Stream	0.4142	0.1575	Drift
R4	Stream	0.4361	0.9511	Runoff

<u>PECsw values for the metabolite M12.</u>

Table B.8.5.2-11: Metabolite M12 winter cereals, early application. Step 3 results Isoflucypram DT_{50} water 1000

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3	Winter cereals early applications DT_{50} water 1000 days, DT_{50} sediment 388 days		
D1	Ditch	0.4044	0.604
D1	Stream	0.2584	0.3468
D2	Ditch	0.487	0.5154
D2	Stream	0.3164	0.3123
D3	Ditch	0.1650	0.4357
D4	Pond	0.4367	0.8620
D4	Stream	0.2194	0.3042
D5	Pond	0.3007	0.6434
D5	Stream	0.1334	0.1626
D6	Ditch	0.1417	0.1479
R1	Pond	0.0187	0.0062
R1	Stream	0.0081	0.0042
R3	Stream	0.03184	0.0109
R4	Stream	0.0159	0.0042

Table B.8.5.2-12: Metabolite M12 winter cereals, late application. Step 3 results Isoflucypram DT_{50} water 1000

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3	Winter cereals late applications DT_{50} water 1000 days, DT_{50} sediment 388 days		
D1	Ditch	0.2046	0.3261
D1	Stream	0.1305	0.1856
D2	Ditch	0.3189	0.3432
D2	Stream	0.2068	0.2097
D3	Ditch	0.1650	0.4356
D4	Pond	0.2114	0.4245
D4	Stream	0.1078	0.1485
D5	Pond	0.1602	0.3458
D5	Stream	0.0733	0.0865
D6	Ditch	0.0653	0.0678
R1	Pond	0.0021	0.0057
R1	Stream	0.1594	0.0080
R3	Stream	0.0387	0.0067
R4	Stream	0.0069	0.0061

Table B.8.5.2-13: Metabolite M12 Spring cereals, early application. Step 3 results Isoflucypram DT_{50} water 1000

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3	Spring cereals early applications DT_{50} water 1000 days, DT_{50} sediment 388 days		
D1	Ditch	0.3904	0.564
D1	Stream	0.2486	0.3247
D3	Ditch	0.2270	0.5943
D4	Pond	0.4145	1.240
D4	Stream	0.1973	0.3136
D5	Pond	0.2859	0.6062
D5	Stream	0.1329	0.1474
R4	Stream	0.0072	0.0066

Table B.8.5.2-14: Metabolite M12 Spring cereals, late application. Step 3 results Isoflucypram DT_{50} water 1000

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3	Spring cereals Late applications DT_{50} water 1000 days, DT_{50} sediment 388 days		
D1	Ditch	0.2514	0.3539
D1	Stream	0.1603	0.2032
D3	Ditch	0.1769	0.4679
D4	Pond	0.2320	0.4705
D4	Stream	0.1151	0.1736
D5	Pond	0.1698	0.3636
D5	Stream	0.0811	0.0874
R4	Stream	0.0074	0.0068

Table B.8.5.2-15: Metabolite M12 Winter cereals, early application. Step 3 results Isoflucypram DT_{50} water 388

Scenario **FOCUS**	**Waterbody**	**Max PEC$_{sw}$ (µg/L)**	**Max PEC$_{sed}$ (µg/kg)**
Step 3	Winter cereals early applications DT_{50} water 388 days, DT_{50} sediment 1000 days		
D1	Ditch	0.4043	0.5605
D1	Stream	0.2599	0.3278
D2	Ditch	0.4823	0.4804
D2	Stream	0.3219	0.2983
D3	Ditch	0.2330	0.6077
D4	Pond	0.4369	0.8611
D4	Stream	0.2195	0.3041
D5	Pond	0.3008	0.6403
D5	Stream	0.1336	0.1623
D6	Ditch	0.1417	0.1461
R1	Pond	0.0021	0.0052
R1	Stream	0.0082	0.0025
R3	Stream	0.0320	0.0069
R4	Stream	0.0162	0.0025

Table B.8.5.2-16: Metabolite M12 winter cereals, late application. Step 3 results Isoflucypram DT_{50} water 388

Scenario **FOCUS**	**Waterbody**	**Max PEC$_{sw}$ (µg/L)**	**Max PEC$_{sed}$ (µg/kg)**
Step 3	Winter cereals late applications DT_{50} water 388 days, DT_{50} sediment 1000 days		
D1	Ditch	0.2046	0.3077
D1	Stream	0.1311	0.1785
D2	Ditch	0.3189	0.3225
D2	Stream	0.2104	0.2009
D3	Ditch	0.1650	0.4355
D4	Pond	0.2115	0.4242
D4	Stream	0.1078	0.1485
D5	Pond	0.1602	0.3458
D5	Stream	0.0733	0.0865
D6	Ditch	0.0653	0.0690
R1	Pond	0.0232	0.0053
R1	Stream	0.0160	0.0049
R3	Stream	0.0389	0.0060
R4	Stream	0.0070	0.0036

Table B.8.5.2-17: Metabolite M12 spring cereals, early application. Step 3 results Isoflucypram DT_{50} water 388

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3	Spring cereals early applications DT_{50} water 388 days, DT_{50} sediment 1000 days		
D1	Ditch	0.3904	0.5298
D1	Stream	0.2495	0.3096
D3	Ditch	0.2770	0.5942
D4	Pond	0.4147	0.8383
D4	Stream	0.1974	0.3135
D5	Pond	0.2860	0.6043
D5	Stream	0.1330	0.1472
R4	Stream	0.0073	0.0037

Table B.8.5.2-18: Metabolite M12 spring cereals, late application. Step 3 results Isoflucypram DT_{50} water 388

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3	Spring cereals late applications DT_{50} water 388 days, DT_{50} sediment 1000 days		
D1	Ditch	0.2514	0.3344
D1	Stream	0.1608	0.1949
D3	Ditch	0.1769	0.4678
D4	Pond	0.2322	0.4701
D4	Stream	0.1152	0.1735
D5	Pond	0.1699	0.3625
D5	Stream	0.0811	0.0873
R4	Stream	0.0076	0.0039

Step 4 calculations have been performed for the scenarios where the PEC at step 3 exceeds the proposed RAC of 0.948µg/L. Exceedance is noted in only the D1 scenario for early applications in winter and spring cereals and D1 and D2 for winter cereals. However entry is driven by drainage as the key route of entry. Current E.U. agreed models do not have any methods of mitigation to reduce entry via drainage. Step 4 calculations have been provided for a 20m spray drift buffer zone to demonstrate that any potential spray drift buffer will provide sufficient mitigation. Calculations were performed for the worst case results predicted at step 3 using a DT50 in water of 388days and DT50 in sediment of 1000 days. Step 4 values are presented in table B.8.5.2-19.

Table B.8.5.2-19: Step 4 values for all scenarios for a 20m spray drift buffer zone.

Scenario **FOCUS**	**Application scenario**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3		Winter cereals early applications DT_{50} water 1000 days, DT_{50} sediment 388 days		
D1	Winter cereals early	Ditch	1.388	17.70
D2	Winter cereals early	Ditch	1.369	12.66
D1	Spring cereals early	Ditch	1.181	17.05

B.8.6. FATE AND BEHAVIOUR IN AIR

B.8.6.1. **Route and rate of degradation in air and transport via air**

The transport via air of isoflucypram was not studied since its vapour pressure is less than the FOCUS air trigger value for short-range transport exposure assessment of 10^{-5} Pa for substances applied to plants.

B.8.6.2. **Predicted environmental concentrations from airborne transport**

The transport via air of isoflucypram was not studied since its vapour pressure is below the FOCUS air trigger value for short-range transport exposure assessment of 10^{-5} Pa for substances applied to plants.

B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

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

B.8.8. REFERENCES RELIED ON

Modelling was submitted by the applicant, however as the endpoints proposed and those agreed were different exposure modelling was conducted by the RMS. No references were relied on.