

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 5400 A

Product name(s): FASHION

Chemical active substance(s):

Fluroxypyr, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

(Authorization)

Applicant: Sharda Cropchem Limited

Submission date: January 2022

MS Finalisation date: August 2023; December 2023;

January 2025

Version history

When	What
January 2022	Application to Ministry of Agriculture and Rural Development as zRMS, as a "no-data" application based on article 33 and 34 of Regulation (EU) No 1107/2009 using data from the existing reference product Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).
August 2023	Applicant update
January 2023	ZRMs evaluated dRR submitted by Applicant
December 2023	ZRMs evaluated an update.
January 2025	The final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

Introduction

FASHION is a herbicide formulated as a emulsion concentrate [EC] containing 250 g/L of Fluroxypyr for professional use. Sharda Cropchem Limited consider that the proposed formulation is comparable to the Dow AgroSciences Polska Sp. z o.o. product Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99) registered in the Poland under Regulation (EC) 1107/2009. The uses and claims for which approval is being sought are the same as those already approved for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99) in the Poland and for which data are unprotected.

Fluroxypyr was renewed and approved under Commission Implementing Regulation (EU) No 736/2011 of 26 July 2011 and was subsequently listed as an approved active substance under Regulation 1107/2009 on 25th May 2011 (Implementing Regulation 540/2011). Data protection on all active substance data submitted on Fluroxypyr expired on 9th October 2015 – 30 months after renewal on 10.04.2013 reference product Starane 250 EC.

As the data protection period has expired for the active substances Fluroxypyr, Sharda Cropchem Limited are making application for authorisation of FASHION on the basis that FASHION and Starane 250 EC are comparable. Starane 250 EC was registered in the Poland more than 10 years ago – on 19.10.1999. Therefore data supporting the national approval of Starane 250 EC in the Poland should no longer be protected.

Consequently, Sharda Cropchem Limited apply for authorisation in accordance with article 33 of Regulation (EU) No 1107/2009, claiming exemption from provision of any study reports allowed for under article 34 of the same regulation.

The proposed Sharda source of Fluroxypyr was evaluated by UK. The GLP 5-batch data was evaluated as part of this applications. The equivalence report is available on CIRCABC. The applicant considers FASHION to be comparable, to Starane 250 EC: details provided in Table 1.2-1 of Draft Registration Report – Part C.

The risk assessment conclusions are based on the information, data and assessments contained within the EU review of Fluroxypyr and the review carried out for the registration of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The data supporting these reviews of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99) are out of protection and therefore maybe accessed by the evaluating authorities. Therefore, no new data nor risk assessment are required and thus not presented in the current dossier.

Therefore, on the assumption that the products FASHION and Starane 250 EC are sufficiently similar, it is entirely valid scientifically to extrapolate from the Starane 250 EC review to support the authorisation of FASHION in the Poland but also elsewhere in the European Union.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

GAP rev. 0, date: January 2022

PPP (product name/code):	FASHION / SHA 5400 A	Formulation type:	EC (Emulsion Concentrate)
Active substance 1:	Fluroxypyr	Conc. of as 1:	250 g/L
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Sharda Cropchem Limited	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	Conclusion PECgw
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat, winter triticale	F	Dicotyledons weeds	Spraying	BBCH 13-37	a) 1 b) 1	-	a) 0,6-0,8 b) 0,6-0,8	a) 0.15 – 0.2 b) 0.15 - 0.2	200-300	-	Tank mixture: 0,3 l/Ha FASHION + 15 g/Ha of Tribenuron methyl 750 g/Kg	Risk mitigation measures required
2	PL	Spring wheat, spring barley	F	Dicotyledons weeds	Spraying	BBCH 13-37	a) 1 b) 1	-	a) 0,6 b) 0,6	a) 0.15 b) 0.15	200-300	-	Tank mixture: 0,3 l/Ha FASHION + 15 g/Ha of Tribenuron methyl 750 g/Kg	Risk mitigation measures required

3.	PL	Grassland	F	Dicotyledons weeds	Spraying	From early spring to middle of September. Weeds in 8-10 cm high or BBCH 13-14.	a) 1 b) 1	-	a) 0,8 b) 0,8	a) 0.2 b) 0.2	200-300	-		A
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Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

(d) Select relevant
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
 2 Use official codes/nomenclatures of EU Member States
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and 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
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions

Explanation for column 15 "Conclusion"

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

The risk mitigation measures required:

Winter Cereals (WC)

BBCH 13

SPe2: To protect ground water apply this product every 3 years in alkaline soils and every 2 years in acidic soils in WC crops.

BBCH 20, 20% interception

SPe2: To protect the ground water apply this product every 3 years from BBCH 20 in alkaline soils in WC crops.

BBCH 30, 80% interception

SPe2: To protect the ground water do not apply this product before BBCH 30 in alkaline soils in WC crops.

Spring Cereals (SC)

BBCH 13

SPe2: To protect the ground water apply this product every 2 years in alkaline soils in SC crops.

BBCH 20, 20% interception

SPe2: To protect the ground water apply this product every 2 years from BBCH 20 in alkaline soils in SC crops.

BBCH 30, 80% interception

SPe2: To protect the ground water do not apply this product before BBCH 30 in alkaline soils in SC crops.

zRMS comment:

All data referred to points 8.2-8.61 are included in report Starane 250 EC Reg. No. R-52/2013 and are in line EFSA Journal 2011; 9(3): 2091 and were accepted by evaluator.

8.2 Metabolites considered in the assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.3 Rate of degradation in soil (KCP 9.1.1)

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Active substance 1 and its metabolites

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Active substance 1 and its metabolites

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.5 Mobility in soil (KCP 9.1.2)

8.5.1 Active substance 1 and its metabolites

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.5.2 Column leaching (KCP 9.1.2.1)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.5.3 Lysimeter studies (KCP 9.1.2.2)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.5.4 Field leaching studies (KCP 9.1.2.3)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

8.6.1 Active substance 1 and its metabolites

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

ZRMS Comments:

The intended GAP for the formulation Starane 250 EC is within those considered acceptable for registration of product FASHION.

The input parameters used in PEC_{soil} calculations for Starane 250 EC are the same as those utilised in the EFSA conclusion (EFSA Journal 2011; 9(3): 2091) and are therefore considered acceptable for FASHION.

Relevant crop interception is not in line with FOCUS groundwater guidance (2014). For winter and spring cereals for BBCH 13-37 should be used 0% interception.
For grassland interception is accepted.

The Applicants' calculations in report Starane were independently validated by the zRMS using the same input parameters and 0% interception and results are presented below:

Crop	Maximum PECs (mg/kg)
------	----------------------

	Fluroxypyr-meptyl	Fluroxypyr
Cereals (winter/spring)	0.384	0.267

The results PEC_{soil} calculations are appropriate for risk assessments in soil for FASHION.
 No further calculations of PEC soil are required.

8.7.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.7.2 Active substance(s) and relevant metabolite(s)

8.7.2.1 Active substance 1 and its metabolites

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.7.2.2 PEC_{soil} of formulation

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

ZRMS Comments:

The intended uses in GAP for the formulation Starane 250 EC are within those considered acceptable for registration of product FASHION.

The input parameters used in PEC_{gw} calculations for Starane were the same as those utilised in the EF-SA conclusion and therefore were considered acceptable.

The new calculations of PEC in ground water for fluroxypyr acid and relevant metabolite has been assessed with standard FOCUS scenarios groundwater modelling FOCUS PEARL ver. 5.5.5 and FOCUS PELMO ver. 6.6.4 by using the EU agreed input parameters and application dates as suggested by App Date 3.06. Relevant crop interception was used is in line with FOCUS groundwater guidance (2014). For winter and spring cereals for BBCH 12-37 was used 0%, 20% and 80% interception. For grassland interception was used 40%.

In connection with the above the results of the groundwater modelling performed for Starane 250 SC with new calculations of PEC_{gw} are acceptable for application of FASHION in winter and spring cereals and grassland as they do meet the current requirements.

However, following mitigation measure should be included in label on national level:

Winter Cereals (WC)
BBCH 13

SPe2: To protect ground water apply this product every 3 years in alkaline soils and every 2 years in acidic soils in WC crops.

BBCH 20, 20% interception

SPe2: To protect the ground water apply this product every 3 years from BBCH 20 in alkaline soils in WC crops.

BBCH 30, 80% interception

SPe2: To protect the ground water do not apply this product before BBCH 30 in alkaline soils in WC crops.

Spring Cereals (SC)

BBCH 13

SPe2: To protect the ground water apply this product every 2 years in alkaline soils in SC crops.

BBCH 20, 20% interception

SPe2: To protect the ground water apply this product every 2 years from BBCH 20 in alkaline soils in SC crops.

BBCH 30, 80% interception

SPe2: To protect the ground water do not apply this product before BBCH 30 in alkaline soils in SC crops.

Grass/Alfalfa

No mitigation measures needed.

8.8.1 Justification for new endpoints

All endpoints are according to EFSA Journal 2011;9(3):2091.

Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1			2			3
Crop	Winter cereals			Spring cereals			Grassland (Grass/Alfalfa)
Application rate (g as/ha)	Fluroxypyr: 200			Fluroxypyr: 150			Fluroxypyr: 200
Number of applications/interval	1/-						
Crop interception (%)	0	20	80	0	20	80	40
Frequency of application	Annual						
Model for calculations	FOCUS PEARL v. 5.5.5 & FOCUS PELMO v. 6.6.4						

It should be noted that as recommended in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (FOCUS 2011), a corrected application rate is calculated taking into account the interception by the crop canopy. Therefore, the substance is applied directly to the ground in the models, thus avoiding the internal interception routines in the models. The corrected application rates are 200 g as/ha, 160 g and

40 g as/ha for winter cereals, 150 g and 120 g as/ha for spring cereals and 120 g as/ha for grassland applications.

Table 8.8-2: Application dates used for groundwater risk assessment

Scenario	Application dates						Grassland (Grass/Alfalfa)
	Winter cereals			Spring cereals			
	BBCH 13	BBCH 20	BBCH 30	BBCH 13	BBCH 20	BBCH 30	
Châteaudun	31/10	10/11	-	16/03	-	-	01/02
Hamburg	06/11	16/11	-	06/04	-	-	
Jokioinen	25/09	-	-	22/05	-	-	
Kremsmünster	10/11	20/11	24/04	06/04	15/04	27/04	
Okehampton	22/10	01/11	-	05/04	-	-	
Piacenza	06/12	-	-	-	-	-	
Porto	10/12	-	-	16/03	-	-	
Sevilla	06/12	-	-	-	-	-	
Thiva	08/12	-	-	-	-	-	

*According to AppDate v3.06 (28 June 2019)

8.8.1.1 Active substance 1 and its metabolites

Table 8.8-3: Input parameters related to active substance Fluroxypyr and its metabolites for PEC_{gw} calculations

Compound	Fluroxypyr	Pyridinol	Methoxyppyridine (DMP)	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	255	197	211	Y, EFSA Journal 2011;9(3):2091
Water solubility (mg/L):	91 (20°C)			
Saturated vapour pressure (Pa):	3.78 x 10 ⁻⁹ (20°C)			
DT ₅₀ in soil (d)	13.1 (geomenan, lab studies, normalisation to pF2, 20°C with Q ₁₀ = 2.58, n = 14)	18.4 (geomean, lab studies, normalisation to pF2, 20°C with Q ₁₀ = 2.58, n = 12)	170.4 (geomean, lab studies, normalisation to pF2, 20°C with Q ₁₀ = 2.58, n = 12)	
K _{foc} (mL/g)/K _{fom}	66.9/38.8 (geomean, n = 4)	1288/747.1 (for acidic/neutral soils) 44.3/25.7 (for	310.9/180.3 (geomean, n = 4)	

Compound	Fluroxypyr	Pyridinol	Methoxy-pyridine (DMP)	Value in accordance with EU endpoint y/n/ Reference*
		alkaline soils)		
I/n	0.93 (arithmetic mean, n = 4)	0.84 (for acid-ic/neutral soils) 1.00 (for alkaline soils)	0.84 (arithmetic mean, n = 4)	
Plant uptake factor	0			
Formation fraction	-	0.286 from parental	0.201 from parental	

Table 8.8-4: FOCUS scenarios soil pH and Kfoc values for Pyridinol

Scenario FOCUS	Soil pH	Kfoc (mL/g)
Châteaudun	8	44.3
Hamburg	6.4	1288
Jokioinen	6.2	1288
Kremsmünster	7.7	44.3
Okehampton	5.8	1288
Piacenza	7	1288
Porto	4.9	1288
Sevilla	7.3	44.3
Thiva	7.7	44.3

Table 8.8-5: FOCUS PELMO 6.6.4 and PEARL 5.5.5 PEC_{gw} for Fluroxypyr and its metabolites for Winter cereals (0% interception and 200 g as/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PELMO			PEARL		
		Fluroxypyr	Pyridinol	DMP	Fluroxypyr	Pyridinol	DMP
Winter cereals	Châteaudun	<0.001	0.080	<0.001	0.001	0.120	0.001
	Hamburg	0.062	0.003	0.098	0.056	0.003	0.115
	Jokioinen	0.008	<0.001	0.002	0.007	<0.001	0.001
	Kremsmünster	0.012	0.230	0.049	0.014	0.277	0.056
	Okehampton	0.085	0.001	0.123	0.081	<0.001	0.113
	Piacenza	0.028	0.001	0.091	0.019	0.001	0.094
	Porto	0.093	<0.001	0.085	0.033	<0.001	0.045
	Sevilla	<0.001	0.005	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	0.026	<0.001	<0.001	0.031	<0.001
	Every other year						
	Châteaudun	-	-	-	-	0.053	-

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PELMO			PEARL		
		Fluroxypyr	Pyridinol	DMP	Fluroxypyr	Pyridinol	DMP
	Hamburg	-	-	-	-	-	0.042
	Kremsmünster	-	0.144	-	-	0.147	-
	Okehampton	-	-	0.051	-	-	0.047
	Every 3 rd year						
	Kremsmünster	-	0.080	-	-	0.103	-

Table 8.8-6: FOCUS PELMO 6.6.4 and PEARL 5.5.5 PEC_{gw} for Fluroxypyr and its metabolites for Winter cereals (BBCH 20, 20% interception and 160 g as/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PELMO			PEARL		
		Fluroxypyr	Pyridinol	DMP	Fluroxypyr	Pyridinol	DMP
Winter cereals	Châteaudun	-	-	-	-	0.098	-
	Hamburg	-	-	-	-	-	0.077
	Kremsmünster	-	0.182	0.083	-	0.209	0.083
	Okehampton	-	-	0.083	-	-	0.083
	Every other year						
	Kremsmünster	-	0.113	-	-	0.114	-
	Every 3 rd year						
	Kremsmünster	-	0.065	-	-	0.079	-

Table 8.8-7: FOCUS PELMO 6.6.4 and PEARL 5.5.5 PEC_{gw} for Fluroxypyr and its metabolites for Winter cereals (BBCH 30, 80% interception and 40 g as/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PELMO			PEARL		
		Fluroxypyr	Pyridinol	DMP	Fluroxypyr	Pyridinol	DMP
Winter cereals	Kremsmünster	-	0.038	-	-	0.038	-

Table 8.8-8: FOCUS PELMO 6.6.4 and PEARL 5.5.5 PEC_{gw} for Fluroxypyr and its metabolites for Spring cereals (0% interception and 150 g as/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PELMO			PEARL		
		Fluroxypyr	Pyridinol	DMP	Fluroxypyr	Pyridinol	DMP

Spring cereals	Châteaudun	<0.001	0.012	<0.001	<0.001	0.020	<0.001
	Hamburg	0.002	<0.001	0.005	0.003	<0.001	0.012
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	0.002	0.139	0.004	0.002	0.148	0.006
	Okehampton	0.005	<0.001	0.016	0.005	<0.001	0.016
	Porto	0.002	<0.001	0.002	<0.001	<0.001	0.001
	Every other year						
	Kremsmünster	-	0.073	-	-	0.082	-

Table 8.8-9: FOCUS PELMO 6.6.4 and PEARL 5.5.5 PEC_{gw} for Fluroxypyr and its metabolites for Spring cereals (BBCH 20, 20% interception and 120 g as/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PELMO			PEARL		
		Fluroxypyr	Pyridinol	DMP	Fluroxypyr	Pyridinol	DMP
Spring cereals	Kremsmünster	-	0.113	-	-	0.124	-
	Every other year						
	Kremsmünster	-	0.059	-	-	0.067	-

Table 8.8-10: FOCUS PELMO 6.6.4 and PEARL 5.5.5 PEC_{gw} for Fluroxypyr and its metabolites for Spring cereals (BBCH 30, 80% interception and 30 g as/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PELMO			PEARL		
		Fluroxypyr	Pyridinol	DMP	Fluroxypyr	Pyridinol	DMP
Spring cereals	Kremsmünster	-	0.027	-	-	0.029	-

Table 8.8-11: FOCUS PELMO 6.6.4 and PEARL 5.5.5 PEC_{gw} for Fluroxypyr and its metabolites for Grassland (40% interception, 120 g as/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PELMO			PEARL		
		Fluroxypyr	Pyridinol	DMP	Fluroxypyr	Pyridinol	DMP
Grassland	Châteaudun	<0.001	<0.001	0.001	<0.001	0.088	0.002
	Hamburg	0.002	<0.001	0.004	0.004	<0.001	0.010
	Jokioinen	0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	0.001	<0.001	0.003	0.001	0.087	0.004
	Okehampton	0.010	<0.001	0.024	0.007	<0.001	0.018
	Piacenza	0.015	0.001	0.052	0.006	<0.001	0.026
	Porto	0.011	<0.001	0.018	0.003	<0.001	0.006
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.013	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.011	<0.001

Due to several new refinements and some mistakes in the risk phrases the applicant have amended the GW conclusions accordingly in this update.

Conclusions:

The Applicant would like to propose the following mitigation measures:

Winter Cereals (WC)

SPe2: To protect the ground water apply this product every 3 years until BBCH 30 in alkaline loam/silt loam soils with a O.M. content ≥3.6% WC crops.

BBCH 13

SPe2: To protect the ground water apply this product every 2 years in sandy soils in WC crops.

SPe2: To protect the ground water apply this product every 2 years in alkaline silty clay loam soils in WC crops.

The next mitigation measures should be applied at national level only because Okehampton is not a relevant scenario in Poland.

SPe2: To protect the ground water apply this product every 2 years in acid loam soils with a O.M. content ≥3.8% in WC crops.

~~SPe2: To protect ground water apply this product every 3 years in alkaline soils and every 2 years in acidic soils in WC crops.~~

~~BBCH 20, 20% interception~~

~~SPe2: To protect the ground water apply this product every 3 years from BBCH 20 in alkaline soils in WC crops.~~

BBCH 30, 80% interception

The use of FASHION doesn't pose any risk for ground water when it's applied from BBCH 30 in WC crops.

~~SPe2: To protect the ground water do not apply this product before BBCH 30 in alkaline soils in WC crops.~~

Spring Cereals (SC)

BBCH 13

SPe2: To protect the ground water apply this product every 2 years in alkaline loam/silt loam soils with a O.M. content $\geq 3.6\%$ soils until BBCH 30 in SC crops.

BBCH 20, 20% interception

SPe2: To protect the ground water apply this product every 2 years from BBCH 20 in alkaline soils in SC crops.

BBCH 30, 80% interception

The use of FASHION doesn't pose any risk for ground water when it's applied from BBCH 30 in SC crops.

~~SPe2: To protect the ground water do not apply this product before BBCH 30 in alkaline soils in SC crops.~~

Grass/Alfalfa

The use of FASHION doesn't pose any risk for ground water when it's applied in grass crops.

~~No mitigation measures needed.~~

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

zRMS comments:

The intended uses in GAP for the formulation Starane 250 EC are within those considered acceptable for registration of FASHION.

The input parameters used in PEC_{gw} calculations for Starane are the same as those utilised in the EFSA conclusion and are therefore considered acceptable for FASHION.

This risk envelope approach provides a maximum PEC_{sw} that covers a range of use of formulation Starane 250 EC in Poland.

These values are considered appropriate to be used for subsequent risk assessments of aquatic organisms.

No further consideration of PEC sw is required.

8.9.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

8.9.2.1 Active substance 1 and its metabolites

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
8.8 (KCP 9.2.4)	-	2023	Predicted Environmental Concentrations in groundwater (PEC _{gw}).	N	Sharda Cropchem Limited

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 Study 1

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).