

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 5400 A

Product name(s): FASHION

Chemical active substance(s):

Fluroxypyr, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: **Sharda Cropchem Ltd**

Submission date: March 2023

MS Finalisation date: August 2023; January 2025

Version history

When	What
March 2023	dRR submission
August 2023	ZRMs evaluated dRR submitted by Applicant
January 2025	The final Registration Report

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are in grey).
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

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: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (^f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)		g or 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	<i>Dicotyledons weeds</i>	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	Acceptable for solo use and not accepted in tank mixture
2	PL	Spring wheat, spring barley	F	<i>Dicotyledons weeds</i>	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	Acceptable for solo use and not accepted in mixture tank
3	PL	Grassland	F	<i>Dicotyledons weeds</i>	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	-	-	Conditionally accepted.

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Fluroxypyr 250 g/L (FASHION; Product code: SHA 5400 A)** containing the active substance fluroxypyr, which has been included into **Annex I of Council Directive 91/414/EEC**.

The SANCO report for Fluroxypyr (SANCO/11019/2011 rev 5) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 14 April 2008.

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.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report: KCP 6.0/001 Biological Assessment Dossier Fluroxypyr 250 EC, Central

Description of the plant protection product

FASHION is a herbicide formulated as a emulsion concentrate [EC]containing 250 g/L of Fluroxypyr for professional se. 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.

According to the GAP, the proposed application rate of Fluroxypyr 250 g/L in spring barley and spring wheat is 0.6 L per hectare (L/ha), in winter wheat and winter triticale 0.6- 0.8 L per hectare (L/ha), and in grassland 0.8 L per hectare (L/ha) with one applications per season. This will deliver 0.15-0.2 kg per hectare. In the current document, results obtained in field trials with fluroxypy 250 EC applied at the recommended dose will be presented where these have been tested against similar dose rates of Fluroxypyr 250 EC reference products currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim of Fluroxypyr 250 EC aginst broadleaved weeds in spring barley, spring wheat, winter wheat and triticale and grassland.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPS
Crop(s)	Target(s)			
Winter cereals (Wheat, Triticale,)	Broadleaved	CEU	0.6-0.8 L/ha	Post-emergence application
Spring cereals (barley, wheat)	Broadleaved	CEU	0.6 L/ha	Post-emergence application
Grassland	Broadleaved	CEU	0.8 L/ha	Post-emergence application

Further details are in the table “All intended uses” in Part B - Section 0.

Description of active substance fluroxypyr

Fluroxypyr 250 g/L EC is an emulsifiable concentrate (EC) formulation containing containing 250 grams per liter (g/L) for use in winter wheat, winter triticale, spring wheat and spring barley.

Mode of action of the active ingredient

Fluroxypyr is a systemic and selective herbicide made from pyridinoxy acid and is used to control annual and perennial broadleaf weeds and woody brush. Fluroxypyr is a member of the pyridine class of herbicides and induces an auxin-type response in susceptible annual and perennial broadleaf weeds (auxin being a type of plant growth hormone).

The mode of action of Fluroxypyr is that it operates like a plant growth regulator by imitating natural plant hormones called auxins. Auxins, which are found in all plant types, are responsible for regulating the amount, type and direction of plant growth, and are mostly found at the tips of plant roots and shoots. Fluroxypyr enters plants that have been treated through the leaves and roots, and replaces natural auxins at binding sites, causing abnormal growth patterns and disrupting the growth processes of the plant.

Information on similar formulations and current approvals

Fluroxypyr formulation containing 250 grams per liter (g/L). Data presented in this dossier is generated using this formulation in comparison with reference product Starane 250 EC. Fluroxypyr is currently registered and formulations throughout Europe and a selection of these are described in table below.

Table 3.2-2: Current approvals of fluroxypyr in the EU Central zone

Country	Product	Active ingredient	Approval number
Austria	Tomigan 200	Fluroxypyr	3479-0
	Tandus	Fluroxypyr	43314-0
Croatia	Pluss	Fluroxypyr	UP/I-320-20/09-01/6 UP/I-320-20/17-03/362
	Starline	Fluroxypyr	
	Starane Forte	Fluroxypyr	
	Tomigan 250 EC	Fluroxypyr	
Denmark	Flurostar 180	Fluroxypyr	613-1
	Starane 333 HL	Fluroxypyr	64-82
	Tomahawk	Fluroxypyr	366-60
France	Starane HD	Fluroxypyr	2160805
	Starane 200	Fluroxypyr	8400600
	Flurostar 200	Fluroxypyr	2100053
Germany	Flurostar 200	Fluroxypyr	008981-00
	Fluroxane 180	Fluroxypyr	006914-66
	Hurler	Fluroxypyr	00A554-00
Ireland	Binder	Fluroxypyr	06737
	Tomahawk 2	Fluroxypyr	05043
Netherlands	Starane Top	Fluroxypyr-meptyl	14706
	Tomahawk 200 EC	Fluroxypyr-meptyl	15280
Poland	Dicolen 200 EC	Fluroxypyr	R-38/2018
	Fluroherb 200 EC	Fluroxypyr	R-19/2011
	Galaper 200 EC	Fluroxypyr	R-18/2011
	Starane 250 EC	Fluroxypyr	R-52/2013
Slovakia	BARCLAY HURLER 200	Fluroxypyr	20-00820-AU
	Galaper 200 EC	Fluroxypyr	17-11-1897
	Starane Forte	Fluroxypyr	14-11-1489
	Tomigan 250 EC	Fluroxypyr	16-11-1751
Spain	Flurostar 200	Fluroxypyr	25462
	Fluxyr 200 EC	Fluroxypyr	25589
	Minstrel	Fluroxypyr	ES-00612
	Starane HL	Fluroxypyr	ES-00160
United Kingdom	Arbiter	Fluroxypyr	18326
	Casino	Fluroxypyr	20181
	Decathlon	Fluroxypyr	19746
	Flurostar 200	Fluroxypyr	17438
	Hudson 200	Fluroxypyr	17749

Description of the target pests

In the following, brief details of the broadleaved weeds assessed in efficacy trials are presented.

The damaging economic effects of broadleaved weeds in cereals are well established, and justification for their control well documented. Fluroxypyr 250 g/L control a number of very important annual broadleaved weeds found in winter and spring cereal crops and grassland. Among the species that are controlled Fluroxypyr 250 g/L are f.ex. Common chickweed (*Stellaria media*), Cleavers (*Galium aparine*), Field pennycress (*Thlaspi arvense*).

All the listed weeds are present throughout or in parts of the Central zone and in relevant EPPO zones. These weed species compete with the crops for light, moisture and nutrients, reducing crop yields and may obstruct harvestability.

Table 3.2-3: Glossary of pests mentioned in the report.

EPPO code	Scientific name	Common name
Broadleaved weeds		
ANTAR	<i>Anthemis arvensis</i>	Corn chamomile
BRSNW	<i>Brassica napus</i>	Oilseed rape (volunteer)
CAPBP	<i>Capsella bursa-pastoris</i>	Shepherd's purse
CENCY	<i>Centaurea cyanus</i>	Cornflower
FUMOF	<i>Fumaria officinalis</i>	Common fumitory
GALAP	<i>Galium aparine</i>	Cleavers
GERPU	<i>Geranium pusillum</i>	Small-flowered cranesbill
PAPRH	<i>Papaver rhoeas</i>	Common poppy
POLCO	<i>Fallopia convolvulus</i>	Black bindweed
STEME	<i>Stellaria media</i>	Common chickweed
THLAR	<i>Thlaspi arvense</i>	Field pennycress
VERHE	<i>Veronica hederifolia</i>	Ivy-leaved speedwell
VERPE	<i>Veronica persica</i>	Common field speedwell
VIOAR	<i>Viola arvensis</i>	Field violet

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Winter wheat	CEU	-	dicotyledon weeds	CEU	-
Winter triticale	CEU	-	dicotyledon weeds	CEU	-
Spring barley	CEU	-	dicotyledon weeds	CEU	-
Spring wheat	CEU	-	dicotyledon weeds	CEU	-
Grassland	-	CEU	dicotyledon weeds	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Poland in 2022 season. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Fluroxypyr 250 EC, 6 efficacy trials were conducted in the North-east (6) EPPO zone.

Table 3.2-5: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MED	MAR	N-E	S-E			
TRZAW	Poland	MED+E			3		2022	GEP	
	Total, Winter wheat (eff.)				3				
HORVS	Poland	MED+E			3		2022	GEP	
	Total, Spring barley (eff.)				3				

In the 6 trials, the level of control obtained by Fluroxypyr 250 EC was assessed on dicotyledonous weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

Climatic zones

Not applicable

Agronomic conditions

Not applicable

The reference products used in the efficacy trials are listed in Table 3.2-6.

Table 3.2-6: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Fluroxypyr reference product					
STARANE 250 EC	EC	Fluroxypyr 250 g/l	0.6 L/ha 0.8 L/ha	Poland	6

Comments of zRMS:	<p>This document was prepared by Applicant for registration the FASHION (product code: SHA 5400 A) containing fluroxypyr (250 g/L). The formulation of this product is an emulsion concentrate (EC).</p> <p>First reported in 1983, fluroxypyr is an agricultural herbicide for the control of annual and perennial weeds in cereals, forage maize and grassland. The active substance fluroxypyr is applied as the meptyl ester, which is hydrolysed to the parent acid in the plant. This is the herbicidally active form, which is translocated rapidly around the plant. The herbicide induces characteristic auxin-type responses, e.g. leaf curling and distortion (Tomlin 2003). Cell elongation is promoted, and RNA synthesis is inhibited (European Commission 1999a). Fluroxypyr is in the Herbicide Resistance Action Committee (HRAC) herbicide Group O, which consists of synthetic auxins which act as indoleacetic acid (IAA), and includes molecules such as dicamba, 2,4-D, triclopyr and quinmerac.</p> <p>FASHION is a herbicide formulated as an 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.</p> <p>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. ZRMs agree with this opinion.</p> <p>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. According to Article 34 of the said regulation, the possibility of using "unprotected" data is permissible when the PPP have comparable performance, i.e., according to the Commission's guideline, any differences between their compositions fall within the category of "non-significant" changes specified in the Commission's guideline. Accordingly, an evaluation of the product FASHION was made, and a clear opinion of the entity was given as to whether it could be considered comparable to the plant protection product STARANE 250 EC (Reg. No. R-52/2013) in light of the aforementioned Commission Guidelines.</p> <p>Poland is a ZRMs. In Poland 54 plant protection products containing fluroxypyr are already registered (on the basis on Register of plant protection products dated 02.08.2023).</p>
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3.2.1 Preliminary tests (KCP 6.1)

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) registered.

Comments of zRMS:	Statement accepted. The active substances of FASHION (product code: SHA 5400 A) containing fluroxypyr 250 g/L EC is registered and have been commonly used in crop protection in EU Countries for many years (since 1983s). Also, a large-scale efficacy trials are available to evaluate the effectiveness of products containing this active compound. Therefore, there was no need for preliminary range-finding tests in the opinion of Evaluator. ZRMs agree with Applicant.
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3.2.2 Minimum effective dose tests (KCP 6.2)

This dossier is based on a bridging trials with a product based on 250 g/L fluroxypyr in EC formulation, The proposed dose rate for FASHION 250 EC delivers comparable amounts of fluroxypyr as compared to the authorised uses of the bridging partner.

Field trials were established in order to determine the minimum effective dose of FASHION 250 EC for the control of broadleaved weeds in cereals and in grassland as claimed in this dossier. In the following, summaries of the performance of FASHION EC on cereals are presented.

The minimum effective dose trials were conducted to assess FASHION 250 EC at the following rates:

- Single application to winter wheat and winter triticale target rate: 0.6-0.8 L/ha
- Single application to spring barley and spring wheat target rate: 0.6 L/ha
- Single application to grassland target rate 0.8 L/ha – trials not presented

FASHION 250 EC was tested at a range of dose rates, but to demonstrate minimum effective dose rate, fluroxypyr was applied at 0.3, 0.45, 0.6, 0.8 L/ha in 6 cereals trials.

Summary and evaluation of Minimum Effective Dose trial results for 0.6-0.8 L/ha Fluroxypyr 250 EC target rate against broadleaved in Winter wheat

In order to prove and to support the requested dose rate of 0.6-0.8 L/ha Fluroxypyr 250 EC [0.15-0.2 kg fluroxypyr per hectare] applied post-emergence for the control of broadleaved weeds, the assessment results of 3 efficacy trials with broadleaved weeds, performed in the North-east EPPO zone in 2022 season, are reported. A Fluroxypyr 250 EC was included in these trials at 0.6-0.8 L/ha to demonstrate the recommended dose rate as well as at a lower than recommended dose rate (0.4 L/ha [0.1 kg fluroxypyr per hectare]). The rates reflect the proposed label rate as well as 50-67% of the full recommended rate of Fluroxypyr 250 EC in winter wheat, in accordance with the EPPO standard PP 1/225(2) '*Minimum effective dose*' and the Central zone efficacy requirements.

The control of frequently occurring broadleaved weeds in winter wheat was assessed at different timings throughout the trial period. In the North-east, the data obtained from the assessment carried out after regrowth of the weeds was considered as the most accurate representation of whole plot product performance and this data is therefore presented in the summary table. 3.2-10 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 14-56 days after post-emergence application in the North-east, EPPO zone. The assessment timing included in the summary is presented in detail in Appendix 5.

North-east EPPO zone

In the North-east EPPO zone, the average control of the assessed weed species at the assessment (56 days after application) was 64.3% following a postemergence application of Fluroxypyr 250 EC at 0.4 L/ha, 74.4 % at 0.6 L/ha and 80.9% at 0.8 L/ha.

When applied at post-emergence, a dose response was observed.

Statistical evaluation revealed that Fluroxypyr at 0.6-0.8 L/ha performed significantly better than the lower dose rate at 17 assessments included in the summary table.

Table 3.2-10: North-east zone: Minimum effective dose of Fluroxypyr 250 EC against broadleaved in Winter wheat

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	No/m2 at assessment Mean (min-max)	Efficacy obtained with Fluroxypyr 250 EC at:		
				0.4 L/ha	0.6 L/ha	0.8 L/ha
Post-emergence application						
STEME	21-31	2	11.6 (9.3-13.8)	81.3 (-)	91.3 (90-92.5)	99 (-)
VIOAR	19-31	2	6.3 (6.0-6.5)	0.0	2.5 (0-5.0)	10.7 (0-21.3)
GALAP	19-31	2	23.8 (21.3-26.3)	83.2 (82.5-83.8)	92.6 (91.3-93.8)	98 (97-99)
CENCY	19-31	2	28.2 (23.8-32.5)	72.6 (68.8-76.3)	85.7 (85-86.3)	93.7 (93-94.3)
GERPU	31	1	9.3	87.5	97	99
VERHE	30-31	1	15.0	66.3	82.5	93
BRSNW	31-33	1	12.5	68.8	85	95.5
FUMOF	19-31	1	6.0	75.0	88.8	94.8
PAPRH	19-31	1	26.3	0.0	0.0	0.0
CAPBP	31	1	13.8	75.0	88.8	98
THLAR	31	1	9.3	73.8	87.5	94.3
ANTAR	31	2	12.6 (11.3-13.8)	86.3 (83.8-88.8)	96.0 (-)	99 (-)
Mean of all assessments		17	15.1	64.3	74.4	80.9

Based on results achieved on broadleaved weeds which were present in 3 winter wheat trials included in the minimum effective dose section, it can be concluded that the recommended doses are optimal to consistently control frequently occurring broadleaved weeds. Fluroxypyr 250 EC should be applied post-emergence under optimal weather- and soil conditions at recommended dose rate.

Summary and evaluation of Minimum Effective Dose trial results for 0.6 L/ha Fluroxypyr 250 EC target rate against broadleaved in Spring barley

In order to prove and to support the requested dose rate of 0.6 L/ha Fluroxypyr 250 EC [0.15 kg fluroxypyr per hectare] applied post-emergence for the control of broadleaved weeds, the assessment results of 3 efficacy trials with broadleaved weeds, performed in the North-east EPPO zone in 2022 season, are reported. A Fluroxypyr was included in these trials at 0.6 L/ha to demonstrate the recommended dose rate as well as at a lower than recommended dose rates (0.3 L/ha [0.075 kg fluroxypyr per hectare] and 0.45 L/ha [0.1125 kg fluroxypyr per hectare]). The rates reflect the proposed label rate as well as 50 and 75% of the full recommended rate of Fluroxypyr 250 EC in spring barley, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

The control of frequently occurring broadleaved weeds in winter wheat was assessed at different timings throughout the trial period. In the North-east, the data obtained from the assessment carried out after re-growth of the weeds was considered as the most accurate representation of whole plot product performance and this data is therefore presented in the summary table. **Błąd! Nie można odnaleźć źródła odwołania.**, therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 14-56 days after post-emergence application in the North-east, EPPO zone. The assessment timing included in the summary is presented in detail in Appendix 5.

North-east EPPO zone

In the North-east EPPO zone, the average control of the assessed weed species at the assessment (28-56 days after application) was 48.5% following a postemergence application of Fluroxypyr 250 EC at 0.3 L/ha, 62.5 % at 0.45 L/ha and 70.5% at 0.6 L/ha.

When applied at post-emergence, a dose response was observed.

Statistical evaluation revealed that Fluroxypyr at 0.6 L/ha performed significantly better than the lower dose rates at 20 assessments included in the summary table.

Table 3.2-11: North-east zone: Minimum effective dose of Fluroxypyr 250 EC against broadleaved in Spring barley

EPPO Code	Weed Growth stage at application [BBCH]		No/m2 at assessment Mean (min-max)	Efficacy obtained with Fluroxypyr 250 EC at:		
	No. of trials			Mean (min-max)		
				0.3 L/ha	0.45 L/ha	0.6 L/ha
Post-emergence application						
CHEAL	10-19	3	11.3 (7-20)	22.1 (7.5-38.8)	37.5 (21.3-57.5)	52.5 (38.8-76.3)
POLCO	10-24	3	10.8 (5-22.5)	35.9 (31.3-45)	54.2 (40-78.8)	62.5 (43.8-91.3)
CAPBP	10-19	2	7.8 (5-10.5)	77.5 (72.5-82.5)	89.4 (83.8-95)	97.2 (94.8-99.5)
VIOAR	10-31	3	7.6 (5-10)	35 (25-48.8)	47.5 (42.5-52.5)	57.1 (52.5-65)
VERPE	10-16	2	5 (-)	36.3 (31.3-41.3)	45 (40-50)	46.9 (41.3-52.5)
GALAP	12-21	2	8 (6-10)	81.9 (81.3-82.5)	96.7 (96.3-97)	100 (-)
STEME	14-24	1	9.3	77.5	90	99
ANTAR	14-18	1	12.5	81.3	94.8	99
VERHE	19-31	1	11.3	68.8	87.5	97
GERPU	12-16	1	5	71.3	95.8	100
PAPRH	12-16	1	5	0.0	2.5	10
Mean of all assessments		20	8.7	48.5	62.5	70.5

Based on results achieved on broadleaved weeds which were present in 3 spring barley trials included in the minimum effective dose section, it can be concluded that the recommended doses are optimal to consistently control frequently occurring broadleaved weeds. Fluroxypyr 250 EC should be applied post-emergence under optimal weather- and soil conditions at recommended dose rate.

Conclusion

Based on results achieved on broadleaved weeds in 6 cereals trials treated with post-emergence application, it can be concluded that to consistently control frequently occurring broadleaved weeds in cereals Fluroxypyr 250 EC should be applied post-emergence at 0.6-0.8 L/ha.

Summary of all uses claimed on the label

Fluroxypyr 250 EC applied post-emergence at 0.6-0.8 L/ha to control broadleaved weeds achieved excellent control of all target weeds. Reducing the application rate of Fluroxypyr 250 EC from the proposed dose rate, resulted in lower levels of efficacy. To ensure that a satisfactory level of control is achieved with the dose rate recommended, it is recommended that Fluroxypyr 250 EC is applied under optimal conditions, i.e. post-emergence of the weeds as well as optimal weather- and soil conditions.

As weeds often occur as a complex of several weeds with different susceptibility towards fluroxypyr, one application of Fluroxypyr 250 E at the recommended rate should be used to efficiently control all weeds claimed on the label.

Data from geassland are not presented in this Biological Dossie, but Sharda Cropchem Limited requests for attention that fluroxypyr has been used in grassland for years that fluroxypyr has been used for years also on grasslands. The same weeds are controlled by fluroxypyr in the different crops. When treating the weeds at similar growth stages, the same level of control would be expected, in all GAP claimed crops

and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem Limited requests that the Zonal Evaluators reads across to the data on the other crop types.

As will be demonstrated in the following section, this document clearly demonstrates that the efficacy and crop safety of Fluroxypyr 250 EC is equivalent to that of the standard fluroxypyr reference products (registered over 10 years ago now out of protection to which it was compared. The applicant therefore wishes to cite the original registrant's data on fluroxypyr now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data

<p>Comments of zRMS:</p>	<p>The proposed GAP is available at Table 3.1 1. There are no proposed changes to the uses currently authorised in the Poland in Starane 250 EC (st. reference product) according to the Uniform principles under PPPR and the proposed doses were considered to be justified. The applicant did provide results from trials carried out in winter wheat and spring barley. Trials methodology is described under section 3.2.3. According to Polish regulations, for registration under Article 34 to be possible, the Applicant must submit at least 1-2 confirmatory studies for each requested use. Applicant submitted 3 efficacy trials for winter wheat and 3 efficacy trials for spring barley. Those trials were performed in Poland (N-E EPPO zone) in 2022. Lack of trials for winter triticale and spring wheat, included in GAP table and label. In our opinion, it seems that the lack of research for winter triticale and spring wheat can be accepted. Due to the fact that these applications are registered in the label of the reference product (Starane 250 EC) and that the Applicant has presented studies confirming efficacy on representative cereal species. These results can be extrapolated to other cereals, especially since in practice weed susceptibility is simply assessed on a group of cereals (winter/spring) and not on individual species. The effectiveness and comparability of both PPP products (FASHION and Stranae 250 EC) on a given group of plants (winter and spring cereals) was finally confirmed.</p> <p>For use on grassland – lack of confirmatory study. Applicant requests for attention that fluroxypyr has been used in grassland for years that fluroxypyr has been used for years also on grasslands. The same weeds are controlled by fluroxypyr in the different crops. When treating the weeds at similar growth stages, the same level of control would be expected, in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem Limited requests that the Zonal Evaluators reads across to the data on the other crop types. However, in the opinion of ZRMs this use cannot be accepted without any confirmatory test. For years, the grassland weed control program has been undergoing changes, although not the ones growers expect. Indeed, these changes consist of an annual reduction in the number of herbicides available for their weed control. Grasslands, for the most part, are combinations of mixtures of different grass species, resistant to dozens of herbicidal active substances. Unfortunately, interest from herbicide manufacturers is minimal. Registered combinations are embarrassingly few, although their range could be very rich, In practice, two active substances are approved for weed control in grassland. Fluroxypyr, which is represented by 54 products. Only a few among them have registration for grassland weed control. For example, Starane 250 EC and Taran 250 EC recommended at a dose of 0.8 l/ha in spring or early autumn, but no later than mid-September, when weeds reach a height of 8-10 cm and produce at least 3-4 leaves proper, or Starane 333 EC recommended at a dose of 0.54 l/ha from March to June, at a time of intensive weed growth. In our opinion, FASHION should be registered conditionally on the basis on data of Starane 250</p>
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EC. Within two years after registration, Applicant should present at least 1-2 con-formatory field trials performed in PL.

Minimum effective dose on cereals on the basis on cofirmatory field studies:

Dose justification in cereals is based on data from winter wheat and spring barley.

Winter wheat: In North-East EPPO zone, FASHION was tested at the maximum recommended dose of 0.8 L product/ha in all trials, but also, at lower rates 0.4 and 0.6 L product/ha. In the North-east EPPO zone, the average control of the assessed weed species at the assessment (56 days after application) was 64.3% following a postemergence application of Fluroxypyr 250 EC at 0.4 L/ha, 74.4 % at 0.6 L/ha and 80.9% at 0.8 L/ha. So, dose 0.6 L/ha and 0.8 L/ha were characterized by similar efficacy against studied weeds species. Only dose 0.4 L/ha has lower efficacy than 0.6 and 0.8 L/ha.

Following weed spesces were studed in those 3 trials: STEME (2), VIOAR (2), GALAP (2), CENCY (2), ANTAR (2), GERPU (1), VERHE (1), BRSSNN (1), FUMOF (1), PAPRH (1), CAPBP (1) and THLAR (1).

Spring barley: In North-East EPPO zone, FASHION was tested at the maximum recommended dose of 0.6 L product/ha in all trials, but also, at lower rates 0.3 and 0.5 L product/ha. In the North-east EPPO zone, the average control of the assessed weed species at the assessment (28-56 days after application) was 48.5% following a postemergence application of Fluroxypyr 250 EC at 0.3 L/ha, 62.5 % at 0.45 L/ha and 70.5% at 0.6 L/ha. So, dose 0.6 L/ha was characterized by the best efficiency against studied weed species.

Following weed spesces were studed in those 3 trials: CHEAL (3), POLCO (3), CAPBP (2), VIOAR (3), VERPE (2), GALAP (2), STEME (1), ANTAR (1), VERHE (1), GERPU (1) and PAPRH (1).

Lack of trials for winter tritcale and spring wheat, included in GAP table and label. In our opinion, it seems that the lack of research for winter tritcale and spring wheat can be accepted. Due to the fact that these applications are registered in the label of the reference product (Starane 250 EC) and that the Applicant has presented studies confirming efficacy on representative cereal species. These results can be extrapolated to other cereals, especially since in practice weed susceptibility is simply assessed on a group of cereals and not on individual species. The effectiveness and comparability of both PPP products (FASHION and Stranae 250 EC) on a given group of plants (winter and spring cereals) was finally confirmed.

The evaluation was conducted according to The Uniform Principles.

The proposed minimum dose is consistent with the dose registered in the reference product (Starane 250 EC) and corresponds to the recommendations for flurozypyr in the cereal's protection program. The grassland dose is also in line with other comparable products on the Polish market.

No results for mixture tank with Granstar 75 WG 15 g/ha (containing Tribenuron methyl) was presented by Applicant. However, in the label, the Applicant included information that *"In order to increase the spectrum of weeds controlled, FASHION can be used in a mixture with Granstar 75 WG until the end of the tillering stage of cereals at a dose of: FASHION 0.3 l/ha + Granstar 75 WG 15 g/ha."* The same claim is included in the label of the reference product (Starane 250 EC) whose unprotected data is used. Since Fashion and Starane are equivalent PPP and their efficacy of solo use is comparable, it can be assumed that with high probability the product mixed with another substance will show even higher efficacy. It is worth noting that on the Polish market most of the registered

	products contain such a recommendation for use in the mixture tank with Granstar 75 WG. But, according to section B1,2 &4 - the product is not intended to be tank mixed and there are no compatibility studies in the attached reports. So, in our opinion this use should be excluded from GAP table. In addition, the applicant failed to provide the required studies confirming its superior efficacy when used in a tank mix (at least 1-2 efficacy studies should have been submitted for winter cereal and spring cereal).
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3.2.3 Efficacy tests (KCP 6.2)

Six efficacy trials conducted in the North-east Eppo to support the proposed label claims of Fluroxypyr 250 EC in the Central zone. The trials were conducted in winter wheat, spring barley.

The efficacy trials were conducted to prove the following label claim:

- Single application to winter wheat and winter triticale target rate: 0.6-0.8 L/ha
- Single application to spring barley and spring wheat target rate: 0.6 L/ha
- Single application to grassland target rate 0.8 L/ha – trials not presented

Table 3.2-12: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (5), PP 1/135(4),PP 225 (2)
	Specific guidelines	PP 1/93 (3)
Experimental design	Plot design	RCBD (6)
	Plot size	15-21 m ²
	Number of replications	4 (6)
Crop	Trials per crop	Spring barley (3) Winter wheat (3)
	Varieties per crop	<u>Spring barley</u> : Propino,Ella,KWS Vermont <u>Winter wheat</u> : Florian,,KWS Chamsin,Etana
	Sowing period	Spring barley: 13/05/22-15/04/22 Winter wheat: 30/09/21-25/10/21
Application	Application period	Spring barley: 31/05/22-26/05/22 Winter wheat: 10/05/22
	Crop stage (BBCH)* at application	Spring barley: 22-32 Winter wheat: 29-31
	Number of appl. Intervals between appl.	1 (6)
	Spray volumes	200 L/ha
Assessment	Assessment types	- Visual estimation of crop injury and crop stand reduction (thinning) compared to ‘untreated’ (‘untreated’ = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate, this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour
	Assessment dates	As a rule 3 crop injury ratings
Other rele-	Soil type	loamy sand, sandy loam

vant information	Organic matter content	1.4-3.7
	Natural / artificial inoculation...	Preferably disease-free conditions
	Field / Greenhouse...	Field

In the 6 trials, the level of control obtained by Fluroxypyr 250 EC was assessed on broadleaved and grass weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

Use 001: Efficacy against broadleaved weeds in Winter wheat, winter triticale

The efficacy trials were conducted to prove the following label claims:

Description of Use 001

Crop	Winter wheat, winter triticale
Use rate	0.6-0.8 L/ha Fluroxypyr 250 EC
Use frequency	Up to 1x
Application timing	BBCH 13-33
Target	Broadleaved weeds

The effectiveness of applying Fluroxypyr 25% EC post-emergence against broadleaved weeds was evaluated in 3 efficacy trials conducted in winter wheat. These trials were carried out in 2022 season in the North-east (Poland). The objective was to confirm the performance of Fluroxypyr 25% EC at 0.6-0.8 L/ha (i.e. 0.15-0.2 kg fluroxypyr per hectare) and compare this to reference product 250 EC. In the trials, one application was applied.

The same weeds are controlled by fluroxypyr in the different crops. When treating the weeds at similar growth stages, the same level of control would be expected, in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem Limited requests that the Zonal Evaluators reads across to the data on the other crop types.

North-east zone

To demonstrate the effectiveness of the test product at the recommended dose rate against broadleaved weeds following post-emergence application in winter wheat as well as compare it to the reference product included in the trials, results are presented in Table 3.2.13.

The data presented in Table 3.2-13 are based on the detailed data presented in Appendix 5 Table 3. The individual trial data can be located in the respective reports cited in the reference list in appendix 1. All data in the respective reports, if considered valid, were included in the detailed data table in Appendix 5.

When applied at 0.6-0.8 L/ha post-emergence in the North-east zone, Fluroxypyr 250 EC achieved moderate to excellent control of broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Fluroxypyr 25% EC was similar to the effect obtained with the fluroxypyr reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

Table 3.2-13: North-east zone – Mean efficacy from 3 trials treated with Fluroxypyr 250 EC and reference product in the North-east Eppo zone (56 days after last treatment; mean and variation in % control as compared to untreated check)

Eppo	Weed	No.	Ground cover at	Efficacy obtained with	No. of trials where	
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Code	Growth stage at application [BBCH]	of trials	assessment min-max	Fluroxypyr 25% EC		Starane 250 EC	Pendimethalin 45.5% CS at 1590 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall		
				Mean (min-max)					>		=	<
				0.6 L/ha	0.8 L/ha	0.8 L/ha						
Pre-emergence application												
STEME	21-31	2	11.6 (9.3-13.8)	91.3 (90-92.5)	99 (-)	98.8 (98.5-99)		0/2*	2/0	</=		
VIOAR	19-31	2	6.3 (6.0-6.5)	2.5 (0-5.0)	10.7 (0-21.3)	11.3 (0-22.5)		1/2	1/0	=		
GALAP	19-31	2	23.8 (21.3-26.3)	92.6 (91.3-93.8)	98 (97-99)	98.3 (97.5-99)		0/2	2/0	</=		
CENCY	19-31	2	28.2 (23.8-32.5)	85.7 (85-86.3)	93.7 (93-94.3)	94.3 (-)		1/2	1/0	</=		
GERPU	31	1	9.3	97	99	99		1/1	-	=		
VERHE	30-31	1	15.0	82.5	93	94.3		0/1	1/0	</=		
BRSNW	31-33	1	12.5	85	95.5	94.8		0/1	1/0	</=		
FUMOF	19-31	1	6.0	88.8	94.8	97		0/1	1/0	</=		
PAPRH	19-31	1	26.3	0.0	0.0	0		1/1	-	=		
CAPBP	31	1	13.8	88.8	98	96		0/1	1/0	</=		
THLAR	31	1	9.3	87.5	94.3	97		0/1	1/0	</=		
ANTAR	31	2	12.6 (11.3-13.8)	96.0 (-)	99 (-)	98.8 (98.5-99)		1/2	1/0	=		
Mean, all assessments		17	15.1	74.4	80.9	81.2		5/16	12/0	=		

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the broadleaved and grass weed spectrum controlled after application of Fluroxypyr 250 EC post-emergence to weeds are listed in Table 3.2-8.

Use 002: Efficacy against broadleaved weeds in Spring wheat and spring barley

The efficacy trials were conducted to prove the following label claims:

Description of Use 002

Crop	Spring wheat, spring barley
Use rate	0.6 L/ha Fluroxypyr 25% EC
Use frequency	Up to 1x
Application timing	BBCH 13-33
Target	Broadleaved weeds

The effectiveness of applying Fluroxypyr 25% EC post-emergence against broadleaved weeds was evaluated in 3 efficacy trials conducted in spring barley. These trials were carried out in 2022 season in the North-east (Poland). The objective was to confirm the performance of Fluroxypyr 25% EC at 0.6 L/ha (i.e. 0.15 kg fluroxypyr per hectare) and compare this to reference product 250 EC. In the trials, one application was applied.

The same weeds are controlled by fluroxypyr in the different crops. When treating the weeds at similar growth stages, the same level of control would be expected, in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem Limited requests that the Zonal Evaluators reads across to the data on the other crop types.

North-east EPPo zone

To demonstrate the effectiveness of the test product at the recommended dose rate against broadleaved weeds following post-emergence application in spring barley as well as compare it to the reference product included in the trials, results are presented in Table 3.2.14.

The data presented in Table 6.2.10 are based on the detailed data presented in Appendix 5 Table 2. The individual trial data can be located in the respective reports cited in the reference list in appendix 1. All data in the respective reports, if considered valid, were included in the detailed data table in Appendix 5.

When applied at 0.6 L/ha post-emergence in the North-east zone, Fluroxypyr 250 EC achieved moderate to excellent control of broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Fluroxypyr 25% EC was similar to the effect obtained with the fluroxypyr reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

Table 3.2-14: North-east zone – Mean efficacy from 3 trials treated with Fluroxypyr 250 EC and reference product in the North-east EPPO zone (28-56 days after last treatment; mean and variation in % control as compared to untreated check)

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with		No. of trials where Pendimethalin 45.5% CS at 1590 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Fluroxypyr 25% EC	Starane 250 EC				
				Mean (min-max)		0.6 L/ha	0.6 L/ha	>	=
Pre-emergence application									
CHEAL	10-19	3	11.3 (7-20)	52.5 (38.8-76.3)	55.0 (42.5-78.8)		3		=
POLCO	10-24	3	10.8 (5-22.5)	62.5 (43.8-91.3)	62.1 (45.0-88.8)		3		=
CAPBP	10-19	2	7.8 (5-10.5)	97.2 (94.8-99.5)	96.8 (93.5-100)		2		=
VIOAR	10-31	3	7.6 (5-10)	57.1 (52.5-65)	56.3 (52.5-62.5)		3		=
VERPE	10-16	2	5 (-)	46.9 (41.3-52.5)	46.9 (42.5-51.3)		2		=
GALAP	12-21	2	8 (6-10)	100 (-)	100 (-)		2		=
STEME	14-24	1	9.3	99	99		1		=
ANTAR	14-18	1	12.5	99	99		1		=
VERHE	19-31	1	11.3	97	97.5		1		=
GERPU	12-16	1	5	100	100		1		=
PAPRH	12-16	1	5	10	10		1		=
Mean, all assessments		20	8.7	70.5	70.7		20		=

Use 003: Efficacy against broadleaved weeds in Grassland

The efficacy trials were conducted to prove the following label claims:

Description of Use 003

Crop	Grassland
Use rate	0.8 L/ha Fluroxypyr 25% EC
Use frequency	Up to 1x
Application timing	From early spring to middle of September. Weeds in 8-10 cm high or
Target	Broadleaved weeds

In this Biological Dossier bridging trials conducted in grassland are not presented.

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.

According to label of product Starane 250 EC fluroxypyr is recommended to cereal winter and spring and also to grassland. 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.

Table 3.2-7: : Broadleaved weed spectrum controlled by 0.6 -0.8 L/ha FLASH 500 SC after pre emergence or early post emergence application, proven by testing results of the applicant from seasons 2022

	<i>Botanical name</i>	EPPO code
Highly Susceptible (95-100% control)	<i>Anthemis arvensis</i>	ANTAR
	<i>Capsella bursa-pastoris</i>	CAPBP
	<i>Stellaria media</i>	STEME
	<i>Veronica hederlifolia</i>	VERHE
	<i>Galium aparine</i>	GALAP
	<i>Brassica napus</i>	BRSNW
Susceptible (85-94.9% control)	<i>Cyanus segetum</i>	CENCY
	<i>Fumaria officinalis</i>	FUMOF
	<i>Thlaspi arvensis</i>	THLAR
	<i>Stellaria media</i>	STEME
	<i>Veronica hederlifolia</i>	VERHE
	<i>Capsella bursa-pastoris</i>	CAPBP
Moderately Susceptible (70 – 84.9 %)	<i>Veronica hederlifolia</i>	VERHE
Moderately tolerant (50 – 69.9 %)	<i>Fallopia convolvulus</i>	CHEAL
	<i>Fallopia convolvulus</i>	POLCO
	<i>Viola arvensis</i>	VIOAR
Tolerant (0-49.9% control)	<i>Papaver rhoeas</i>	PAPRH
	<i>Viola arvensis</i>	VIOAR
	<i>Veronica presica</i>	VERPE
	<i>Chenopodium album</i>	CHEAL

Summary and conclusion

Summary and conclusion

Based on the results of 6 field trials carried out in 2022, the following can be concluded for the intended use ‘Control of broadleaved weeds’ from FASHION 250 EC applied post-emergence at the dose rate of 0.6 – 0.8 L/ha.

- FLASH 500 SC provides a high level control of dicotyledonous weeds, like f.ex.: *Anthemis arvensis*, *Capsella buesa-pastoris*, *Stellaria media*, *Veronica hederifolia*, *Galium aparine*, *Thlaspi arvensis*, *Fumaria officinalis*
- Compared to the fluroxypyr reference product, the efficacy obtained with FASHION 250 EC is comparable against all weed species.
- The trial results are considered valid for all intended North-east zone

FASHION 250 EC is suitable for the control of broadleaved weeds in cereals and grassland

This BAD also clearly demonstrates that the efficacy and cropsafetyness of FASHION 250 EC is equivalent to the efficacy and cropsafetyness of the standard diflufenican reference products against which FASHION 250 EC was compared. The applicant therefore wishes to cite the original registrant’s data on fluroxypyr now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant’s data and requests that the Zonal Evaluator extrapolate from those

Susceptibility	Abbreviation	Level of control
Highly Susceptible	HS	95-100 %
Susceptible	S	85 – 94.9 %
Moderately Susceptible	MS	70 – 84.9 %
Moderately tolerant	MT	50 – 69.9 %
Tolerant	T	0 – 49.9 %

Table 3.2-8: Broadleaved weed spectrum controlled by 1.25 L/ha Iodosulfuron 0.79% + Fenoxaprop 6.32% + Mefenapyr 2.37% EC after post-emergence application to weeds, proven by testing results of the applicant in 2015, 2016 and 2017.

EPPO code	Scientific name	North-east
ANTAR	<i>Anthemis arvensis</i>	HS
CAPBP	<i>Capsella bursa-pastoris</i>	HS/S
STEME	<i>Stellaria media</i>	HS
VERHE	<i>Veronica hederifolia</i>	HS
GALAP	<i>Galium aparine</i> <i>Brassica napus</i>	HS
BRSNW	<i>Anthemis arvensis</i>	HS
CENCY	<i>Cyanus segetum</i>	S
FUMOF	<i>Fumaria officinalis</i>	S
THLAR	<i>Thlaspi arvensis</i>	S
STEME	<i>Stellaria media</i>	S
VERHE	<i>Veronica hederifolia</i>	S/MS
CHEAL	<i>Chenopodium album</i>	MT
POLCO	<i>Fallopia convolvulus</i>	MT
VIOAR	<i>Viola arvensis</i>	MT/T

Comments of zRMS: All details about efficacy methodology used during efficacy trial are presented

	<p>above by Applicant. Submitted reports from field trials include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc.</p> <p>Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Considering Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 applicant provides three bridging, efficacy trials carried out on winter wheat and 3 trials on spring barley, to confirm that properties of FASHION are comparable to properties of Starane 250 EC in protection against weed species.</p> <p><u>The following efficacy scale was used by Evaluator:</u></p> <ul style="list-style-type: none">- L – limiting (0-60% efficacy)- ME – moderately efficiency (60-80%)- E – efficiently (>80%) <p>We are dealing with the active substance used commonly for many years in many countries. Applicant submitted trials carried out in 2022. These studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized. Appropriate window application, number of applications and water volume was studied during those trials.</p> <p>In the opinion of ZRMs, only three trials on winter wheat and 3 trials on spring barley are sufficient to show a comparable efficiency of Starane 250 EC (whose unprotected data are used) and FASHION (claimed PPP). These trials can be considered as valid. Level of infestation was at acceptable level (requested was at least 5%).</p> <p>For use on <i>grassland</i> – lack of confirmatory study. Applicant requests for attention that fluroxypyr has been used in grassland for years that fluroxypyr has been used for years also on grasslands. The same weeds are controlled by fluroxypyr in the different crops. When treating the weeds at similar growth stages, the same level of control would be expected, in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem Limited requests that the Zonal Evaluators reads across to the data on the other crop types. However, in the opinion of ZRMs this use cannot be accepted without any confirmatory test. For years, the grassland weed control program has been undergoing changes, although not the ones growers expect. Indeed, these changes consist of an annual reduction in the number of herbicides available for their weed control. Grasslands, for the most part, are combinations of mixtures of different grass species, resistant to dozens of herbicidal active substances. Unfortunately, interest from herbicide manufacturers is minimal. Registered combinations are embarrassingly few, although their range could be very rich, In practice, two active substances are approved for weed control in grassland. Fluroxypyr, which is represented by 54 products. Only a few among them have registration for grassland weed control. For example, Starane 250 EC and Taran 250 EC recommended at a dose of 0.8 l/ha in spring or early autumn, but no later than mid-September, when weeds reach a height of 8-10 cm and produce at least 3-4 leaves proper, or Starane 333 EC recommended at a dose of 0.54 l/ha from March to June, at a time of intensive weed growth. In our opinion, FASHION should be registered conditionally on the basis on data of Starane 250 EC. Within two years after registration, Applicant should present at least 1-2 confirmatory field trials performs in PL.</p> <p><u>Efficacy from bridging trials:</u></p> <ul style="list-style-type: none">• <i>winter wheat</i> – following weed species were studied during trials: STEME
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	<p>(2), VIOAR (2), GALAP (2), CENCY (2), ANTAR (2), GERPU (1), VERHE (1), BRSNW (1), FUMOF (1), PAPRH (1), CAPBP (1) and THLAR (1).</p> <p>Susceptible weeds at dose 0.8 L/ha: STEME, GALAP, CENCY, GERPU, VERHE, BRSNW, FUMOF, CAPBP, THLAR and ANTAR. Tolerant weeds at 0.8 L/ha: VIOAR, PAPRH.</p> <p>Susceptible weeds at dose 0.6 L/ha: STEME, GALAP, CENCY, GERPU, BRNW, FUMOF, CAPBP, THLAR, ANTAR. Moderately susceptible weeds at 0.6 L/ha: VERHE. Tolerant weeds at 0.6 L/ha: VIOAR, PAPRH.</p> <ul style="list-style-type: none">• <i>spring barley</i> – following weed species were studied during trials: CHEAL (3), POLCO (3), CAPBP (2), VIOAR (3), VERPE (2), GALAP (2), STEME (1), ANTAR (1), VERHE (1), GERPU (1), PAPRH (1). <p>Susceptible weeds at dose 0.6 L/ha: CAPBP, GALAP, STEME, ANTAR, VERHE, GERPU. Moderately tolerant weeds at dose 0.6 L/ha: POLCO. Tolerant weeds at dose 0.6 L/ha: CHEAL, VIOAR, PAPRH, VERPE.</p> <p>Data demonstrated that the efficacy of the FASHION at the proposed rate of 0,6-0.8 L/ha for winter cereals (winter wheat) and 0.6 L/ha for spring cereals (spring barley) was equivalent to the efficacy of Starane 250 EC at rate 0,8 L/ha against weed species. All results were comparable to standard reference product: Starane 250 EC.</p> <p>The proposed recommended dose is consistent with the dose registered in the reference product (Starane 250 EC) and corresponds to the recommendations for fluroxypyr in the cereal's protection program. The grassland dose is also in line with other comparable products on the Polish market.</p> <p>No results for mixture tank with Granstar 75 WG 15 g/ha (containing Tribenuron methyl) was presented by Applicant. However, in the label, the Applicant included information that <i>“In order to increase the spectrum of weeds controlled, FASHION can be used in a mixture with Granstar 75 WG until the end of the tillering stage of cereals at a dose of: FASHION 0.3 l/ha + Granstar 75 WG 15 g/ha.”</i> The same claim is included in the label of the reference product (Starane 250 EC) whose unprotected data is used. Since Fashion and Starane are equivalent PPP and their efficacy of solo use is comparable, it can be assumed that with high probability the product mixed with another substance will show even higher efficacy. It is worth noting that on the Polish market most of the registered products contain such a recommendation for use in the mixture tank with Granstar 75 WG. However, given the formal requirements that each application should be proven by an efficacy study. But, according to section B1,2 &4 - the product is not intended to be tank mixed and there are no compatibility studies in the attached reports. So, in our opinion this use should be excluded from GAP table. In addition, the applicant failed to provide the required studies confirming its superior efficacy when used in a tank mixture (at least 1-2 efficacy studies should have been submitted for winter cereal and spring cereal).</p>
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Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.2.4 Summary and Conclusions

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) registered.

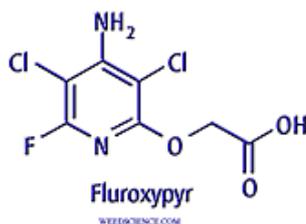
3.2.5 Mode of Action

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) registered.

Fluroxypyr induces auxin-type responses in susceptible annual and perennial broadleaf weeds (auxin being a type of plant growth hormone). Once absorbed into the plant, it accumulates in growing tissues to higher concentrations than the native auxin does, and degrades more slowly. Plant growth is disrupted by the deregulation of cellular growth process following binding of fluroxypyr to plant cell auxin receptor sites. Fluroxypyr also interferes with the plant's ability to metabolize nitrogen and produce enzymes. When a plant's strict growth regulation is disrupted in this fashion, plant growth becomes disorganized, disrupting key metabolic process and results in plant death. Auxin Mimics - HRAC GROUP 4 (Legacy HRAC Group O)

The chemical structure of fluroxypyr is shown in **Błąd! Nie można odnaleźć źródła odwołania..**

Figure 0-1: Structure of fenoxaprop-P-ethyl (Source: Heap, I.; The International Survey of Herbicide Resistant Weeds. Online. Internet. , March 14th, 2023. Available www.weedscience.com)



3.2.6 Mechanism(s) of resistance

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) registered.

3.2.7 Evidence of resistance

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) registered.

3.2.8 Cross-resistance

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) registered .

3.2.9 Sensitivity 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) registered .

3.2.10 Use pattern

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) registered .

3.2.11 Resistance Risk Assessment of unrestricted use patterns

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) registered .

3.2.12 Acceptability of the resistance risk

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) registered .

3.2.13 Implementation of the management strategy

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) registered .

3.2.14 Monitoring, reporting and reaction to changes in performance

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) registered .

Comments of zRMS:	According to Applicant: 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) registered. However, ZRMs presented below some information's on the occurrence or possible occurrence of the development of resistance.
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Mode of action: First reported in 1983, fluroxypyr is an agricultural herbicide for the control of annual and perennial weeds in cereals, forage maize and grassland. The active substance fluroxypyr is applied as the meptyl ester, which is hydrolysed to the parent acid in the plant. This is the herbicidally active form, which is translocated rapidly around the plant. The herbicide induces characteristic auxin-type responses, e.g., leaf curling and distortion (Tomlin 2003). Cell elongation is promoted, and RNA synthesis is inhibited (European Commission 1999a). Fluroxypyr is in the Herbicide Resistance Action Committee (HRAC) herbicide Group O, which consists of synthetic auxins which act as indoleacetic acid (IAA), and includes molecules such as dicamba, 2,4-D, triclopyr and quinmerac.

In soil, fluroxypyr is rapidly degraded, with a lab DT₅₀ of 3-55 days. This means that weeds are exposed to sublethal doses of fluroxypyr for a limited period, thereby reducing the potential for the generation of resistant biotypes.

Resistance Risk Analysis to Fluroxypyr Since fluroxypyr was first described in 1983, there have been 6 (Canada- 2 cases, USA-2 cases, China – 2 cases) reported examples of resistance to fluroxypyr in weeds in agriculture. There are no cases of resistance to fluroxypyr reported in Europe.

The mechanism of resistance in the few cases observed remains currently unknown. Cross-resistance to herbicides with other modes of action has not been observed in fluroxypyr resistant biotypes.

Inherent Product Risk Most broadleaved weeds are regarded as being of minimal risk, with regard to the development of resistant biotypes (PSD Efficacy Guideline 606, May 2008).

FASHION is intended for use as a post-emergence herbicide to control named annual broadleaved weeds in cereals and named broadleaved annual and perennial weeds in grassland.

Agronomic Risk Analysis It is possible that the use of this product in a repeated fashion on the same fields, without any rotation of crops or the use of any mixtures or sequences with any herbicides with different modes of action, could generate resistant biotypes of some weeds (ex: *G. tetrahit* or *S. media*). Although the risk of this is extremely low.

The resistance management strategy proposed by the ZRMs is the use of the product as part of a crop production programme which follows the principles of Good Agricultural Practice. This would include the use of crop rotation, and the use of herbicides of differing modes of action, either in combination with FASHION or in sequence with that product. This was also included in the label project of FASHION.

The inherent risk is low and the use pattern does not contain any parameters that particularly favour the development of weed resistance against FASHION. The target species are regarded as of low potential for the generation of resistant biotypes. The product gives effective control of many broadleaved weed species, and may be used alone or in sequence with other herbicides of different modes of action. The agronomic risk for resistance development in cereals and grassland is therefore considered low.

Conclusions on risk of the possible occurrence of the development of resistance or cross-resistance The risk for the development of resistance of target species were analysed following EPPO guideline PP1/213(1). It is highly unlikely that the use of these products would cause the development of resistant weed biotypes, due to the mode of action of the herbicide product. The product itself has such a low risk of the development of resistance, that the overall risk is low. No specific resistance management strategy is required. It is recommended that the

	user strictly acts according to the guidelines provided with the instructions of use for FASHION. A label phrase is recommended on national level. The evaluation was conducted according to The Uniform Principles.
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3.3 Adverse effects on treated crops (KCP 6.4)

Data from 6 efficacy and 6 selectivity trials conducted in the North-east EPPO zone (Poland) in 2022 season have been included in this biological assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.

The trials were conducted in cereals, where Fluroxypyr 25% EC was applied post-emergence, when the majority of the crop was at BBCH 13-33.

Information on trials submitted (3.4 Adverse effects on treated crops)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

Table 3.3-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MED	MAR	N-E	S-E			
TRZAW	Poland	Q + Y + S			3		2022	GEP	Post-emergence
	Total, Winter wheat (sel)				3				
HORVS	Poland	Q + Y + S			3		2022	GEP	Post-emergence
	Total, Spring barley (sel)				3				

Table 3.3-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (5), PP 1/135(4), PP 1/225(2)
	Specific guidelines	EPPO PP 1/93 (3)
Experimental design	Plot design	RCBD (6)
	Plot size	24-30 m ²
	Number of replications	4 (6)
Crop	Trials per crop	Spring barley (3) Winter wheat (3)
	Varieties per crop	<u>Spring barley</u> : Ella (2).KWS Vermont <u>Winter wheat</u> : Findus,Julius,Florian
	Sowing period	Spring barley: 23/03/22-05/04/22 Winter wheat: 30/09/21 - 25/10/21

Application	Application period	Spring barley: 13/05/22-23/05/22 Winter wheat: 09/05/22-10/05/22
	Crop stage (BBCH)* at application	Spring barley: 25-30 Winter wheat: 30-31
	Number of appl. Intervals between appl.	1 (6)
	Spray volumes	200 L/ha
Assessment	Assessment types	<ul style="list-style-type: none"> - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate, this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour
	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	loamy sand, sandy loam
	Organic matter content	1.2-3.7
	Natural / artificial inoculation...	Preferably weed-free conditions
	Field / Greenhouse...	Field

Reference products

In the efficacy trials with selectivity results, the performance of Fluroxypyr 250 EC was measured against a reference product Starane 250 EC. The trials were carried out on spring barley and winter wheat.

The reference products used in the trials are listed in Table 3.3-3.

Table 3.3-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Ethephon + Mepiquat reference product					
STARNE 250 EC	EC	Fluroxypyr 250g/l	0.6 L/ha 1.2 L/ha 0.8 L/ha 1.6 L/ha	PL	6

3.3.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of Fluroxypyr 250 EC was assessed in Cereals in 6 efficacy trials and 6 selectivity trials all in North east EPPO zone. Fluroxypyr 250 EC was applied at 0.3, 0.45, 0.6, 0.8, 1.2 and 1.6 L/ha. In the efficacy- and selectivity trials conducted in cereals, Fluroxypyr 25% EC was applied post-emergence.

The trials were conducted in the the North-east EPPO zone (i.e. Poland (6 eff. and 6 sel.) in 2022 season, to evaluate the crop safety of Fluroxypyr 25% EC in Cereals.

3.3.1.1 Summary and evaluation of winter wheat trials treated post-emergence

The crop safety of applying ~~Iodosulfuron 0.79% + Fenoxaprop 6.32% + Mefenapyr 2.37% EC post-emergence of the crop in winter wheat was evaluated in 31 efficacy trials (6 MED, 9 MAR, 4 S-E and 12 N-E) and 24 selectivity (6 MED, 6 MAR, 4 NE and 8 SE). Fluroxypyr 250 EC in winter wheat was studied in 6 selectivity trials and 6 efficacy trials carried out in 2022 in Poland.~~

Spring barley

Crop phytotoxicity was evaluated in efficacy trials where Fluroxypyr 250 EC was applied at one application when the crop was at growth stages ranging from BBCH 24 to BBCH 31, at the rate of in spring barley at 0.3, 0.45 and 0.6 L per hectare (L/ha) and in selectivity trials at 0.6 and 1.2 L/ha when the crop was at growth stages ranging from 25-30 BBCH. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in Spring barley, North- east EPPO zone

A total of 3 efficacy and 3 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Fluroxypyr 250 EC when applied as recommended in Spring barley. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 3 efficacy (3) and selectivity (3) trials treated with Fluroxypyr 250 EC in the North-east EPPO zone.

Winter wheat

Crop phytotoxicity was evaluated in efficacy trials where Fluroxypyr 250 EC was applied at one application when the crop was at growth stages ranging from BBCH 29 to BBCH 31, at the rate of in spring barley at 0.4,0.6 and 0.8 L per hectare (L/ha) and in selectivity trials at 1.2 and 1.6 L/ha when the crop was at growth stages ranging from 30-31 BBCH. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in Winter wheat, North- east EPPO zone

A total of 3 efficacy and 3 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Fluroxypyr 250 EC when applied as recommended in Winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 3 efficacy (3) and selectivity (3) trials treated with Fluroxypyr 250 EC in the North-east EPPO zone.

Overall conclusion

Spring barley and winter wheat are claimed on the label. The claims of crop safety on spring barley and winter wheat are supported with a total of 12 trials conducted in Poland in 2022. In all trials, Fluroxypyr 250 EC applied at the proposed label recommended rates in cereals proved to be crop safe and in selectivity trials with double dose rate did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range.

As the data on spring barley and winter wheat show, the crop safety and efficacy of Fluroxypyr 250 EC is equivalent to that of the standard formulated reference products tested in the trials (Starane 250 EC).

Table 3.3-4: Phytotoxicity of product, efficacy and selectivity trials

Number of trials with...		Efficacy trials (6 trials)		Selectivity trials (6 trials)	
		Test product	Standard	Test product	Standard
		1 N	1N	2N	2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	6	6	6	6
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	6	6	6	6
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Comments of zRMS:	Considering Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation
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	<p>1107/2009 applicant provides six bridging, efficacy trials (3-winter wheat, 3-spring barley) and 6 selectivity trials (3-winter wheat, 3-spring barley), to confirm that properties of FASHION are comparable to properties Starane 250 EC in safety for cereals.</p> <p>The efficacy trials in which phytotoxicity effects about tested plant protection product has been carried out in accordance with EPPO-Guidelines. The conduct of the field work is principally compliant with “Good Agricultural Practice“ and in accordance with EPPO Guidelines PP 1/135. The appropriate experimental design was applied. In this study product was compared to the standard reference products. Statistical analysis of the data was performed. No phytotoxicity symptoms caused by FASHION at the proposed dose rates of 0.6 L/ha for spring cereals and 0.6-0.8 L/ha for winter cereals were recorded. Lack of trials for winter triticale and spring wheat. However, in the opinion of ZRMs it should be accepted. No phytotoxicity effect was observed on studied cereals and reference product is registered for use on winter wheat, winter triticale and spring barley and spring wheat. Therefore, it can be assumed with high probability that the product will not cause side effects in these crops. During selectivity trials: dose N and 2 N was studied. No adverse effects in regard to phytotoxicity and vigour were observed in any of the efficacy (6) and selectivity (6) trials treated with Fluroxypyr 250 EC in the North-east EPPO zone on winter wheat and spring barley. For grassland – no selectivity trials were required.</p> <p>As the data on spring barley and winter wheat show, the crop safety and efficacy of Fluroxypyr 250 EC is equivalent to that of the standard formulated reference products tested in the trials (Starane 250 EC).</p> <p>No results for mixture tank with Granstar 75 WG 15 g/ha (containing Tribenuron methyl) was presented by Applicant. However, in the label, the Applicant included information that <i>“In order to increase the spectrum of weeds controlled, FASHION can be used in a mixture with Granstar 75 WG until the end of the tillering stage of cereals at a dose of: FASHION 0.3 l/ha + Granstar 75 WG 15 g/ha.”</i> The same claim is included in the label of the reference product (Starane 250 EC) whose unprotected data is used. Since Fashion and Starane are equivalent PPP and their efficacy of solo use is comparable, it can be assumed that with high probability the product mixed with another substance will show even higher efficacy and a comparable level of security for crops. It is worth noting that on the Polish market most of the registered products contain such a recommendation for use in the mixture tank with Granstar 75 WG. However, given the formal requirements that each application should be proven by an efficacy/selectivity study (at least 1 for each use- on winter cereal and spring cereal), we can not agree to registration in tank mixture. Also, according to section B1,2 &4 - the product is not intended to be tank mixed and there are no compatibility studies in the attached reports. So, in our opinion this use should be excluded from GAP table.</p>
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3.3.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Six selectivity trials were conducted to obtain selectivity results with the same formulation currently under registration, Fluroxypyr 250 EC, in the North-east EPPO zone (Poland (6)) on the quality of the harvested crop of spring barley and winter wheat. The results obtained in the 6 trials are presented in the section below.

All trials conducted on cereals presented in this Biological Assessment Dossier were located within the North-east zone (6), as defined by EPPO Standard PP1/241(1).

3.3.2.1 Summary and evaluation of the field trials conducted in Spring barley

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in Table 3.4-5. The summary table is based on yield data presented in Appendix 6.

A total of 3 selectivity trials in spring barley were harvested. The trials were conducted in Poland in 2022 (3). In this trials, Fluroxypyr 250 EC was applied at 0.6 and 1.2 L/ha, The trials were sprayed at crop growth stages ranging between BBCH 25 and BBCH 30.

Table 3.3-5: North-east zone – Crop yield (T-met) of spring barley treated with luroxypyr 250 EC, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Fluroxypyr 25% EC		Ref. product	Ref. product
		Mean (min-max)	% relative, compared to untreated (min-max, no. of trials)			
		T met	0.6 L/ha	1.2 L/ha	1N	2 N
Spring barley – Efficacy trials, all reference products						
North-east Eppo zone	3	6.47 (5.67-6.88)	97.1 (92.0-102.6)	97.2 (93.6-102)	98.5 (97.0-101.2)	96.8 (93.0-99.3)

3.3.2.2 Summary and evaluation of the field trials conducted in Winter wheat

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in **Błąd! Nie można odnaleźć źródła odwołania.**6. The summary table is based on yield data presented Appendix 6 .

North-east

A total of 3 selectivity trials in winter wheat were harvested. The trials were conducted in Poland (3) in 2022. In the efficacy trials, Fluroxypyr 25% EC was applied at 0.8, 1.6 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 29 and BBCH 31. In **Błąd! Nie można odnaleźć źródła odwołania.** 9 the results obtained in the efficacy trials when treated with 0.8 and 1.6 L/ha are presented.

Table 3.3-6: North-east zone – Crop yield (t/ha) of winter wheat treated with luroxypyr 250 EC, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Fluroxypyr 25% EC		Ref. product	Ref. product
		Mean (min-max)	% relative, compared to untreated (min-max, no. of trials)			
		T met	0.8 L/ha	1.6 L/ha	1 N	2N
Winter wheat – Selectivity trials, all reference products						
North east Eppo zone	3	8.3 (7.63-9.12)	100.5 (99.7-101.4)	99.3 (97.5-100.5)	99.1 (97.2-101.6)	100.5 (99.3-101.2)

3.3.2.3 Conclusion

Fluroxypyr 250 EC applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, spring barley and winter wheat did not affect crop yield significantly in any of the 6 trials harvested. In all selectivity trials as, Fluroxypyr 250 EC applied at recommended and double dose rates did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that Fluroxypyr 250 EC is as safe to the crop as the reference products used in the trials.

For recommendations on the label not sufficiently supported with trials harvested, the applicant wishes to bridge to the trials conducted in spring barley and winter wheat where harvest data demonstrated the safe use following application of Fluroxypyr 250 EC as recommended. Furthermore, the data presented in this BAD also clearly demonstrates that the efficacy and crop safety of Fluroxypyr 250 EC is equivalent to the standard reference products to which it was compared. The applicant therefore wishes to cite the original registrant's data on fluroxypyr now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>Considering Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 Applicant provides six bridging, efficacy trials (3-winter wheat, 3-spring barley) and 6 selectivity trials (3-winter weat, 3-spring barley), to confirm that properties of FASHION are comparable to properties of Starane 250 EC in the effect on the yield.</p> <p>Fluroxypyr 250 EC applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, spring barley and winter wheat did not affect crop yield significantly in any of the trials harvested. In all selectivity trials as, Fluroxypyr 250 EC applied at recommended and double dose rates did not significantly affect the crop yield.</p> <p>Applicant should present trials for tank mixture with Granstar 75WG. At least one trial for spring and winter cereals. Lack of trials for this use, so it should be excluded from GAP table and label project.</p>
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3.3.2.4 Relationship between phytotoxicity and yield

No significant reductions in crop yield were recorded in the vast majority of the plots treated with Fluroxypyr 250 EC at dose rates representative of the recommended dose rate or the 2N rate in the trials in which adverse effects were observed.

Comments of zRMS:	ZRMs agree with Applicant.
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3.3.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Six efficacy trials treated with Fluroxypyr 250 EC were harvested and yields recorded.. Besides recording yield, assessments were also carried out on the potential impact of treatment on a range of quality parameters including moisture content or Weifre. The summary table is based on yield quality data presented in Appendix 6.

The materials and methods of these trials are described in Section 3.3.

Spring barley

In the trials evaluated, Fluroxypyr 250 EC had no detrimental effect on the quality parameters assessed on the harvested spring barley grains. When comparing the results obtained with Fluroxypyr 250 EC against the results obtained with the formulated reference product at comparable dose rates, both products

performed statistically similar on all quality parameters assessed.

Table 3.3-7 North-east zone – Quality of harvested spring barley grains – crop treated with Fluroxypyr 250 EC in selectivity trials, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Fluroxypyr 250 EC		Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			Mean (min-max)	0.6 L/ha	1.2 L/ha	1 N
Spring barley – Selectivity trials, , North-east EPPO zone						
MOICON	3	10.97 (10.7-11.1)	100.6 (99.1-102.7)	100.9 (99.1-103.7)	99.7 (97.3-100.9)	101.8 (97.3-104.5)
HLW	3	58.91 (53.8-68.2)	99.9 (98.1-103.4)	101.3 (100.5-101.9)	99.8 (96.3-103.2)	102.5 (99.5-104.8)
TGW	3	45.11 (44.7-45.9)	99.9 (99.4-100.7)	99.4 (99.3-99.5)	98.8 (97.3-99.7)	98.9 (97.7-99.6)
PROCON	3	9.09 (8.2-9.6)	100 (97.3-105)	105.6 (98.7-108.3)	100 (97.7-101.8)	99.7 (95.1-102.1)

In the trials evaluated, Fluroxypyr 250 EC had no detrimental effect on the quality parameters assessed on the harvested spring barley. When comparing the results obtained with Fluroxypyr 250 EC against the results obtained with the standard reference product at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

Winter wheat

In the trials evaluated, Fluroxypyr 250 EC had no detrimental effect on the quality parameters assessed on the harvested winter wheat grains. When comparing the results obtained with Fluroxypyr 250 EC against the results obtained with the formulated reference product at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

Table 3.3-8 North-east zone – Quality of harvested winter wheat grains – crop treated with Fluroxypyr 250 EC in selectivity trials, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Fluroxypyr 250 EC		Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			Mean (min-max)	0.8 L/ha	1.6 L/ha	1 N
Winter wheat – Selectivity trials, , North-east EPPO zone						
MOICON	3	11.97 (11.7-12.2)	100.8 (98.3-104.1)	97.7 (94.9-103.3)	100.8 (100-101.7)	98.6 (95.8-102.5)
HLW	3	81.3 (80.2-82.3)	100.2 (99.4-100.7)	100.1 (98.2-101)	100 (99-100.5)	100.4 (99.9-100.6)
TGW	3	49.2 (48.3-50)	99.7 (97.8-101)	99.5 (98.4-100.4)	98.1 (96.3-100.2)	100.5 (99.8-101.4)
PROCON	3	11.9 (11.6-12.1)	102 (100-106)	102 (100-105.2)	103.1 (100.8-104.1)	99.9 (96.6-104.1)

In the trials evaluated, Fluroxypyr 250 EC had no detrimental effect on the quality parameters assessed on the harvested winter wheat. When comparing the results obtained with Fluroxypyr 250 EC against the results obtained with the standard reference product at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

3.3.3.1 Conclusion

Fluroxypyr 250 EC applied at the proposed and double dose rate, at a range of growth stages within the label recommended rate, in spring barley and winter wheat did not significantly affect the quality of the harvested crop in any of the 6 trials harvested. In all efficacy trials as, Fluroxypyr 250 EC applied at recommended and double dose rates did not significantly affect the quality of the harvested crop either.

Furthermore, the data obtained in trials harvested demonstrate that Fluroxypyr 250 EC is as safe to the crop as the reference products used in the trials.

As this BAD clearly demonstrates, the efficacy and crop safety of Fluroxypyr 250 EC is equivalent to the standard reference products to which it was compared. The applicant therefore wishes to cite the original registrant's data on Fluroxypyr 250 EC now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>Considering Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 applicant provides six bridging, efficacy trials and 6 selectivity trials, to confirm that properties of FASHION are comparable to properties of Starane 250 EC in the effect on quality of the yield.</p> <p>Fluroxypyr 250 EC applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, spring barley and winter wheat did not affect crop quality of yield significantly in any of the trials harvested. In all selectivity trials as, Fluroxypyr 250 EC applied at recommended and double dose rates did not significantly affect the crop yield.</p> <p>Applicant should present trials for tank mixture with Granstar 75WG. At least one trial for spring and winter cereals should be presented. Lack of trials, so this use should be excluded from GAP table and label project.</p>
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3.3.4 Effects on transformation processes (KCP 6.4.4)

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) registered.

Comments of zRMS:	<p>EPPO standard PP 1/243 ('Effects of plant protection products on transformation processes') defines a processing procedure as any process used for the transformation of the harvested crop into the final product dependent in whole or in part on biological activity. This is distinguished from processing that is purely physical and/or chemical in nature, which may impact on the quality of the processed product but does not affect the process itself.</p> <p>Of those crops relevant to this application, only processes associated with the production of commodities from cereal crops meets the above criteria. In view of the fact that fluroxypyr is a herbicide, and therefore is not expected to have any effect on the biological components of processing procedures associated with cereals, as well as the long, problem-free history of use of similar products in Europe, the risk of effects on processing procedures is considered to be low. Based on this, further investigation of the effects of treatments with FASHION (product code: SHA 5400 A) were considered unnecessary in the opinion of ZRMs.</p>
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3.3.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

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) registered.

The product complies with the Uniform Principles.

Comments of zRMS:	FASHION has been shown to be comparable to the referenced product, STARANE 250 EC. In view of the long, problem-free history of use of similar
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	products in Europe, the risk of effects on plants used for propagating purposes is considered to be low. Residue levels in the crops listed on the FASHION label should be presented in the Residue section. Based on this, further investigation of the effects of treatments with FASHION were considered unnecessary in the opinion of ZRMs.
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3.4 Observations on other undesirable or unintended side-effects (KCP 6.5)

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) registered.

3.4.1 Impact on succeeding crops (KCP 6.5.1)

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) registered.

Comments of zRMS:	<p>Fluroxypyr is rapidly degraded in soil, with a DT₅₀ of 5-9 days in laboratory soil studies (Tomlin, 2003). Consequently, the ZRMs proposes that no work is required to determine the safety to potential succeeding crops.</p> <p>Further information on the fate and behaviour of the active substance in FASHION in the soil should be found in the relevant section in the fate and behaviour dossiers submitted for this product.</p> <p>In addition to the above, in view of the long, problem-free history of use of similar products in Europe, the risk of effects on succeeding crops overall is considered to be low. Based on this, further investigation of the effects of treatments with FASHION were considered unnecessary in the opinion of ZRMs.</p>
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3.4.2 Impact on other plants including adjacent crops (KCP 6.5.2)

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) registered.

Comments of zRMS:	<p>FASHION has been shown to be comparable to the referenced product, STARANE 250 EC. In view of the long, problem-free history of use of similar products in Europe, the risk of effects on adjacent plants is considered to be low when the product is used correctly and according to the proposed GAP. Appropriate measures to limit drift onto other crops are and should continue to be practised. Based on this, further investigation of the effects of treatments with FASHION were considered unnecessary in the opinion of ZRMs.</p>
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3.4.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

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) registered .

Comments of zRMS:	<p>The efficacy concerns relate mainly to beneficial species used as part of IPM. Therefore, as the proposed uses are not reliant on IPM, the ecotoxicological data and endpoints for non-target organisms were not critical to satisfy the data re-</p>
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	quirement.
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3.4.4 Tank cleaning

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) registered .

Relevant information on tank cleaning is included in dRR Part B124. Please refer to this section for complete evaluation.

Comments of zRMS:	FASHION has been shown to be comparable to the referenced product, STARANE 250 EC. ZRMs agree with Applicant that 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) registered
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3.5 Other/special studies

No other studies were conducted.

Comments of zRMS:	ZRMs agree with Applicant.
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3.6 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

Table 3.6-1: List of test facilities

Testing facility	Zone	Country	Year and trial type	Year and trial type
			2022	2022
			Efficacy	Selectivity
Spring barley				
GBA Poland	NE	PL	3	3
Total, Spring barley			3	3
Winter wheat				
GBA Poland	NE	PL	3	3
Total, Winter wheat			3	3

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
KCP 6.0-001	Anonymous	2023	Biological Assessment Dossier Fluroxypyr 250 EC– EU Central zone Sharda Cropchem Limited -, - Unpublished	N	Sharda