

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 5400 A

Product name: FASHION

Chemical active substance:

Fluroxypyr, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: January 2022

MS Finalisation date: September 2023; December 2023;
January 2025

Version history

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

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

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

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

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

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

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

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

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

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland FASHION	-
Southern zone	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Fluroxypyr

Table 0.1-2: Summary of regulatory history of CAS No: 69377-81-7

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) 736/2011 of 26 July 2011
RMS	RMS: SE coRMS:SI
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2012
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2012
Date of final Commission (re-registration) deadline (Step 2)	31.12.2015
Current expiration of approval	31.12.2024
Low risk substance or Candidate for Substitution?	N/A

The SANCO report for Fluroxypyr (SANCO/11019/2011 rev 5, 23 March 2017) 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.

Table 0.1-3: Information on minimum purity of Fluroxypyr

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
950 g/kg	minimum purity of active substance: 985 g/kg Equivalence report available: Yes, evaluation RMS: UK

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Efficacy section: 1-3

Residues section: 1-3

Environmental fate and behaviour section: 1-3

Ecotoxicology section: 1-3

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none

Residues section: none

Environmental fate and behaviour section: none.

Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

Fate section: uses 1-2 mitigation measure is necessary for winter cereals and spring cereals

Residues section: All uses/ GAPs are covered by established MRLs

zRMS main conclusions :

Efficacy section:

Solo use of FASHION on spring cereals (wheat and barley) and winter cereals (wheat and triticale) was accepted. Use in tank mixture with Granstar 75 WG 15 g/ha on cereals (winter wheat, winter triticale, spring barley, spring wheat) was not accepted, but use on grassland was conditionally accepted.

Mammalian toxicology:

No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC.

Therefore classification of FASHION is:

Asp. Tox. 1/H304 – May be fatal if swallowed and enters airways

STOT SE 3/H335 - May cause respiratory irritation

STOT SE3 /H336 - May cause drowsiness or dizziness.

Carc.2/H351 - Suspected of causing cancer.

EUH066: Repeated exposure may cause skin dryness or cracking

No risk for operator, worker and bystander/resident (On base STARANE 250 because FASHION is rated as comparable to STARANE 250 (reg. no R- 52/2013, and previously no. 634/99)

Residues section:

Uses are accepted

EFSA recommends avoiding rotation with root and tuber crops (in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite)

Tank mixture with safener (Granstar 75 WG) is acceptable.

Environmental fate and behaviour section:

No risk for groundwater is expected after application FASHION according GAP. However mitigation measure are required.

Ecotoxicology section:

No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.1.3 are in line EFSA Journal 2011; 9(3): 2091. The evaluation of the application for FASHION resulted in the decision to grant the authorization. However, according to EU Reg. 284 /2009, the chronic toxicity test for adult bees as well as the chronic test for larvae should be provided for authorisation of plant protection product. The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level.

Appendix 1 ALL intended uses

GAP rev. 0, date: January 2022

PPP (product name/code): FASHION / SHA 14800 B
Active substance 1: Fluroxypyr
Active substance 2:
Safener: -
Synergist: -
Applicant: Sharda Cropchem Limited
Zone(s): CEU
Verified by MS: yes/no

Formulation type: EC (Emulsion Concentrate)
Conc. of as 1: 250 g/L
Conc. of as 2:
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Winter wheat, winter triticale	F	Dicotyledons weeds	Spraying	BBCH 13-37	a) 1 b) 1	-	a) 0,6-0,8 b) 0,6-0,8	a) 0.15 – 0.2 b) 0.15 - 0.2	200-300	-	Tank mixture: 0,3 l/ha FASHION + 15 g/ha of Tribenu- ron-methyl 750 g/kg Eff. Section: not accepted use in tank mixture

2	PL	Spring wheat, spring barley	F	Dicotyledons weeds	Spraying	BBCH 13-37	a) 1 b) 1	-	a) 0,6 b) 0,6	a) 0.15 b) 0.15	200-300	-	Tank mixture: 0,3 l/Ha FASHION + 15 g/Ha of Tribenuron methyl 750 g/Kg Eff. Section: not accepted use in tank mixture
3.	PL	Grassland	F	Dicotyledons weeds	Spraying	From early spring to middle of September Weeds in 8-10 cm high or BBCH 13-14.	a) 1 b) 1	-	a) 0,8 b) 0,8	a) 0.2 b) 0.2	200-300	-	Eff. Section: conditionally accepted use
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
-													
-													
Minor uses according to Article 51 (zonal uses)													
-													
-													
Minor uses according to Article 51 (interzonal uses)													
-													
-													

Remarks table heading:

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

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

7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8	The maximum number of application possible under practical conditions of use must be provided.
9	Minimum interval (in days) between applications of the same product
10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13	PHI - minimum pre-harvest interval
14	Remarks may include: Extent of use/economic importance/restrictions