

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 5400 A

Product name: FASHION

Chemical active substance:

Fluroxypyr, 250 g/L

Central

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Sharda Cropchem Limited

Submission date: January 2022

Update: March 2023

**MS Finalisation date: September 2023; December 2023; August 2024;
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).
March 2023	Applicant update
September 2023	ZRMs evaluated dRR submitted by Applicant
December 2023	Correction by the expert.
August 2024	Expert verification of PPP labelling
January 2025	The final Registration Report

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

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.

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

There are no study reports accompanying this application for authorisation in accordance with the art. 34 of the Regulation 1107/2009. Reference is made to data and risk assessments supporting the approval of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). Access to this data is claimed. However this dossier relies also on new physical and chemical tests and studies, providing data and information specific to the formulation Fluroxypyr 2500 g/L SL as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No.1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 5400 A
Product name in MS	FASHION
Authorization number	First registration
Function	Herbicide
Applicant	Sharda Cropchem Limited
Active substance(s) (incl.content)	Fluroxypyr, 250 g/L
Formulation type	Emulsion concentrate [Code: EC]
Packaging	0,25; 0,5; 1; 5; 10; 20 l HDPE/PA (COEX)
Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for FASHION resulted in the decision to grant the authorization.
FASHION is considered to be comparable to Starane 250 EC.

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.

Toxicology 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.

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:

All 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).

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.

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Asp.Tox.1,Carc. 2, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label** is formatted bold:

Hazard pictograms:	GHS07, GHS08, GHS09
Signal word:	Danger
Hazard statement(s):	H304, H351, H335, H336, H400, H410

Precautionary statement(s):	P201+P202, P261, P264, P271, P280, P302+P352, P304+P340, P305+P351+P338, P308+P313, P391, P405, P501
Additional labelling phrases:	Repeated exposure may cause skin dryness or cracking. [EUH066] To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH066	Repeated exposure may cause skin dryness or cracking.
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe2	<p><u>Winter Cereals</u> BBCH 13: To protect ground water apply this product every 3 years in alkaline soils and every 2 years in acidic soils BBCH 20: To protect the ground water apply this product every 3 years from BBCH 20 in alkaline soils BBCH 30: To protect the ground water do not apply this product before BBCH 30 in alkaline soils <u>Spring Cereals</u> BBCH 13: To protect the ground water apply this product every 2 years in alkaline soils in BBCH 20: To protect the ground water apply this product every 2 years from BBCH 20 in alkaline soils BBCH 30: To protect the ground water do not apply this product before BBCH 30 in alkaline soils</p> <p><u>Zboża ozime</u> BBCH 13: W celu ochrony wód gruntowych produkt stosować co 3 lata na glebach zasadowych i co 2 lata na glebach kwaśnych BBCH 20: W celu ochrony wód gruntowych stosować ten produkt co 3 lata od BBCH 20 na glebach alkalicznych BBCH 30: W celu ochrony wód gruntowych nie stosować tego produktu przed BBCH 30 na glebach zasadowych <u>Zboża jare</u> BBCH 13: W celu ochrony wód gruntowych stosować ten produkt co 2 lata na glebach zasadowych BBCH 20: W celu ochrony wód gruntowych stosować ten produkt co 2 lata od BBCH 20 na glebach alkalicznych BBCH 30: W celu ochrony wód gruntowych nie stosować tego produktu przed BBCH 30 na glebach zasadowych</p>
SPe3	To protect aquatic organisms, maintain unsprayed 1 m buffer zone from water bodies and water courses.
SPe3	To protect plants and non-target arthropods, it is necessary necessary respect an unsprayed vegetated buffer zone of 1 m to non agricultural lands.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	-
Worker protection:	
-	-
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 0, date: January 2022

PPP (product name/code): FASHION / SHA 5400 A
Active substance 1: Fluroxypyr
Active substance 2:
Safener: -
Synergist: -
Applicant: Sharda Cropchem Limited
Zone(s): Poland
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.

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

Remarks columns:

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

(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/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

However Applicant presents also studies which have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of yellowish brown liquid with an aromatic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 64.5 °C. It has self-ignition temperature above 350°C. In aqueous solution, it has a pH value around 5.88 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for an *Emulsion concentrate* formulation.

The intended concentration of use is 0.2 % to 0.4 % (v/v).

3.2 Efficacy (Part B, Section 3)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.3 Efficacy data

All details about efficacy methodology used during efficacy trial are presented 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.

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.

The following efficacy scale was used by Evaluator:

- L – limiting (0-60% efficacy)
- ME – moderately efficiency (60-80%)
- E – efficiently (>80%)

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.

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%).

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 EC. Within two years after registration, Applicant should present at least 1-2 confirmatory field trials performed in PL.

Efficacy from bridging trials:

- **winter wheat** – following weed species were studied during trials: STEME (2), VIOAR (2), GALAP (2), CENCY (2), ANTAR (2), GERPU (1), VERHE (1), BRSNW (1), FUMOF (1), PAPRH (1), CAPBP (1) and THLAR (1).

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.

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.

- **spring barley** – 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).

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.

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.

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.

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. However, given the formal requirements that each application should be proven by an efficacy study (at least 1 study for winter cereal (ex. wheat and spring cereal (ex. wheat), so 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.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

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.

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

3.3.2 Adverse effects on treated crops

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 wheat, 3-spring barley), to confirm that properties of FASHION are comparable to properties Starane 250 EC in safety for cereals.

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.

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).

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 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 study for winter cereal (ex. wheat and spring cereal (ex. wheat), so 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.

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.

Applicant should present trials for tank mixture with Granstar 75WG. At least one trial for spring and winter cereals should be presented.

3.3.3 Observations on other undesirable or unintended side-effects

Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. However, some needed information's are presented below by ZRMs:

Effect on transformation processes: 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.

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.

Effect on propagation: 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 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.

Impact on succeeding crops. 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.

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.

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.

Impact on other plants including adjacent crops 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.

Effects on beneficial and other non-target organisms 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 requirement.

3.4 Methods of analysis (Part B, Section 5)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.4.1 Analytical method for the formulation

The determination of the active ingredient is performed by HPLC and it has been developed and sufficiently validated.

Methods suitable for the determination of Fluroxypyr -1-methyl heptyl ester in plant protection product FASHION/SHA 5400 A

	Fluroxypyr -1-methyl heptyl ester
Author(s), year	G.B. Azeema, 2021
Principle of method	HPLC -UV
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	6 points 20.01 mg/L – 33.02 mg/L (30-50 % w/v) $y = 47554x - 17132$ $R^2 = 0.9980$
Precision – Repeatability Mean n = 10 (%RSD)	36.0041% w/v %RSD = 0.0076 %RSD _R = 2.34 %RSD _r = 1.56 Hr = $0.0049 \leq 1$
Accuracy n = 9 (% Recovery)	Fortification level – F1 (20.01 mg/L) – 98.2261% Fortification level – F2 (21.01 mg/L) – 98.0836% Fortification level – F3 (22.01 mg/L) – 99.5330% Total mean recovery: 98.6142 %
Interference/ Specificity	No interference: the method is specific
Comment	-

Methods suitable for the determination of the relevant impurities in plant protection product (PPP) FASHION/SHA 5400 A

	1-Methyl-2-pyrrolidone
Author(s), year	G.B. Azeema, 2021
Principle of method	HPLC-UV
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	6 points 0.1101 mg/L – 5.2047 mg/L (0.0032 – 0.15% w/v) $y = 9365.3x - 28.394$ $R^2 = 0.9998$
Precision – Repeatability Mean n = 10 (%RSD)	0.0994 % w/v %RSD = 0.5002 %RSD _R = 5.66 %RSD _r = 3.79 Hr = $0.131 \leq 1$
Accuracy n = 9 (% Recovery)	Fortification level – F1 (0.1101 mg/L) – 100.4337% - LOQ level Fortification level – F2 (2.6023 mg/L) – 101.2858% Fortification level – F3 (3.3030 mg/L) – 99.3261%

	1-Methyl-2-pyrrolidone
	Total mean recovery: 100.3485%
Interference/ Specificity	No interference: the method is specific
LOQ	0.1316 mg/L
Comment	-

According to SANCO/3030/99 rev. 5 the methods were successfully validated and are suitable for determination of active substance Fluroxypyr-1-methyl heptyl ester and relevant impurity 1-Methyl-2-pyrrolidone in the product FASHION (Fluroxypyr 25% EC).

3.4.2 Analytical methods for residues

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps (minor) are:

- Fluroxypyr:
 - methods (primary and ILV) for drinking water,
 - methods for the analysis of body fluids and tissues.

These data gaps can be covered after authorisation within 2 years.

Commodity/crop	Supported/ Not supported
Cereals / high starch commodity	Supported
Grassland / high water commodity	Supported

3.5 Mammalian toxicology (Part B, Section 6)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

The FASHION classification is derived from a calculation based on the classification of the active compounds and co-formulants.

3.5.1 Acute toxicity

Because FASHION is rated as comparable to Starane 250 WE (reg. no. R-52/2013, and previously no. 634/99), the FASHION classification is based on the results of tests carried out for STARANE.

So the classification for product FASHION (SHA 5400 A) is

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

H335/ STOT.3; May cause respiratory irritation

H336/ STOT.3; May cause drowsiness or dizziness

H351/ Carc.2; Suspected of causing cancer.

EUH066: Repeated exposure may cause skin dryness or cracking

3.5.2 Operator exposure

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

According to the Registration Report Part B3 2016 STARANE 250 EC Total exposure for mixing/loading wearing gloves and applicator (without gloves) is accepted . GF-192 can be safely applied with an air spray”.

3.5.3 Worker exposure

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

According to Registration Report Part B3 2016 STARANE 250 EC Estimated systemic exposure for reintroduction into agricultural uses without wearing protective clothing immediately after application is accepted

Estimated systemic exposure when re-entering the turf (adults and children), without wearing protective clothing immediately after accepting the application is accepted.

3.5.4 Bystander and resident exposure

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

According to the Registration Report Part B3 2016 STARANE 250 EC Based on British and German experimental data, the potential exposure of a bystander/resident following the use of a boom sprayer is accepted.

3.6 Residues and consumer exposure (Part B, Section 7)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

The preparation FASHION (SHA 5400) A is composed of Fluroxypyr.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Fluroxypyr					
ADI	EFSA	2011	0.8 mg/kg bw/day	2-year rat study	100
ARfD	EFSA	2011	Not established, not required.		

3.6.1 Residues

Proposed uses are acceptable.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (Reg. (EU) 2022/1363).

The proposed uses of Fluroxypyr in the formulation Fluroxypyr 25% EC do not represent unacceptable chronic risks for the consumer.

According to the available data there is no risk for animal MRLs to be exceeded.

Confined studies conducted with ¹⁴C-fluroxypyr-MHE at a dose rate of 594 to 676 g a.s./ha (c.a. 3N) indicate that significant residues are not expected to be present in rotational crops.

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

Tank mixture with safener (Granstar 75 WG 15 g/ha) is acceptable.

Re-entry period (in days) for livestock, to areas to be grazed and withholding period (in days) for animal feedingstuffs – 7 days.

3.6.2 Consumer exposure

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.7% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IENTI (% ARfD) according to EFSA PRIMo*	Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

The proposed uses of Fluroxypyr in the formulation Fashion do not represent unacceptable chronic risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009. Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

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

However, following mitigation measure should be included in label:

Winter Cereals (WC)

BBCH 13

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

BBCH 20, 20% interception

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

BBCH 30, 80% interception

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

Spring Cereals (SC)

BBCH 13

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

BBCH 20, 20% interception

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

BBCH 30, 80% interception

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

Grass/Alfalfa

No mitigation measures needed.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.8 Ecotoxicology (Part B, Section 9)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.8.1 Effects on terrestrial vertebrates

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.8.2 Effects on aquatic species

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.8.3 Effects on bees

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.8.4 Effects on other arthropod species other than bees

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

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.

3.8.5 Effects on non-target soil meso- and macrofauna

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.8.6 Effects on soil organisms

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.8.7 Effects on non-target terrestrial plants

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.8.8 Effects on other terrestrial organisms (Flora and Fauna)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

3.9 Relevance of metabolites (Part B, Section 10)

The FASHION formulation is considered comparable to that of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The applicant relies on unprotected data supporting Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), as allowed for under article 34 of Regulation (EU) No 1107/2009.

Please refer to data on Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant. FASHION contains Fluroxypyr which is not approved as candidate for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.
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Appendix 2 Copy of the product label

Sekcja właściwości fizyczne i chemiczne:

Usunięto zwrot H226 i piktogram GHS02; środek nie jest palny

Los i zachowanie w środowisku: Wprowadzono następujące ograniczenia ryzyka:

Zboża ozime

BBCH 13: W celu ochrony wód gruntowych produkt stosować co 3 lata na glebach zasadowych i co 2 lata na glebach kwaśnych

BBCH 20: W celu ochrony wód gruntowych stosować ten produkt co 3 lata od BBCH 20 na glebach alkalicznych

BBCH 30: W celu ochrony wód gruntowych nie stosować tego produktu przed BBCH 30 na glebach zasadowych

Zboża jare

BBCH 13: W celu ochrony wód gruntowych stosować ten produkt co 2 lata na glebach zasadowych

BBCH 20: W celu ochrony wód gruntowych stosować ten produkt co 2 lata od BBCH 20 na glebach alkalicznych

BBCH 30: W celu ochrony wód gruntowych nie stosować tego produktu przed BBCH 30 na glebach zasadowych.

Sekcja pozostałości

Wprowadzono zmianę w akapicie „następstwo roślin”:

Po zbiorze roślin uprawnych można uprawiać wszystkie rośliny z wyjątkiem roślin korzeniowych i bulwiastych.

Sekcja skuteczności

Nie akceptujemy zastosowania w mieszaninie zbiornikowej (ten zapis został z etykiety usunięty). Użytki zielone – akceptujemy tylko warunkowo.

Sekcja toksykologii, ekotoksykologii: Wszystkie zapisy w etykiecie zostały zaakceptowane. Nie wprowadzono żadnych zmian.

According to the study for viscosity which shows that is $\geq 20.5 \text{ mm}^2/\text{s}$, therefore the product does not get the additive trigger value of the classification for H304 according to Regulation (EC) no. 1272/2008

Załącznik do zezwolenia MRiRW nr R -.../2022 z dnia2022 r.

Posiadacz zezwolenia:

Sharda Cropchem Limited, Prime Business Park, Dashrathlal Joshi Road, Vile Parle (West), Mumbai – 400 056, Indie, Tel.: + 91 22 6261 5615, Fax: + 91 22 6678 2828/ 2808, e-mail: regn@shardaintl.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

.....

FASHION

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

fluoksypyr (związek z grupy pochodnych kwasów pirydynokarboksylowych) - 250 g/l (24,77%)

Substancje stwarzające zagrożenie nie będące substancjami czynnymi:

Solwent nafta (ropa naftowa), węglowodory lekkie aromatyczne; niskowrząca benzyna - niespecyfikowana, dichlorometan.

Zezwolenie MRiRW nr R-..../2022 z dnia/2022 r.



Niebezpieczeństwo

H226	Łatwopalna ciecz i pary.
H304	Połyknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.
H335	Może powodować podrażnienie dróg oddechowych.
H336	Może wywoływać uczucie senności lub zawroty głowy.
H351	Podejrzewa się, że powoduje raka.
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH066	Powtarzające się narażenie może powodować wysuszenie lub pękanie skóry.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P210	Przechowywać z dala od źródeł ciepła/ iskrzenia/otwartego ognia/gorących powierzchni. Palenie wzbronione.
P261	Unikać wdychania rozpylonej cieczy.
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P301 + P310	W PRZYPADKU POŁKNIECIA: Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.
P331	NIE wywoływać wymiotów.
P304 + P340	W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
P308+P313	W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P370 + P378	W przypadku pożaru: użyć rozproszonego strumienia wody, proszku gaśniczego, piany lub dwutlenku węgla do gaszenia.
P391	Zebrać wyciek.

OPIS DZIAŁANIA

FASHION jest herbicydem w formie koncentratu do sporządzania emulsji wodnej, stosowanym nalistnie, przeznaczonym do powschodowego zwalczania chwastów dwuliściennych w pszenicy ozimej, pszenicy ozimym, pszenicy jarej, jęczmieniu jarym i na użytkach zielonych. Zgodnie z klasyfikacją HRAC substancja czynna zaliczana jest do grupy O.

DZIAŁANIE NA CHWASTY

FASHION jest herbicydem selektywnym o działaniu układowym, pobierany jest poprzez liście chwastów, a następnie przemieszczanym do dalszych części rośliny powodując ich zamieranie. Fluroksypyr blokuje działanie auksyn, powodując tym samym wstrzymanie syntezy aminokwasów i białek, co w konsekwencji prowadzi do zahamowania wzrostu rośliny.

Pierwsze objawy działania środka na chwasty są widoczne po upływie 2-3 dni od zabiegu. Zamieranie chwastów następuje po 5-7 dniach.

Chwasty wrażliwe:	gorczyca polna, gwiazdnica pospolita, jasnota różowa, maruna bezwonna, przetacznik polny, przytulia czepna, rumian polny, szarłat szorstki, tobołki polne.
Chwasty średniowrażliwe:	fiólek polny, jasnota purpurowa, komosa biała, pokrzywa zwyczajna, samosiewy rzepaku, stulicha psia.
Chwasty średnioodporne	mak polny, mniszek pospolity, przetacznik bluszczykowy, szczaw zwyczajny
Chwasty odporne:	ostrożeń polny.

STOSOWANIE ŚRODKA

STOSOWANIE ŚRODKA

Środek FASHION przeznaczony jest do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych i opryskiwaczy ręcznych.

Pszenica ozima, pszenżyto ozime.

Termin stosowania: środek stosować wiosną, po ruszeniu wegetacji od fazy 3 liści zbóż do początku fazy liścia flagowego zbóż (BBCH 13 – 37).

Maksymalna dawka do jednorazowego stosowania: 0,8 l/ha

Zalecana dawka do jednorazowego zastosowania: 0,6 – 0,8 l/ha

Dawkę środka należy dostosować do fazy rozwojowej przytuli czepnej i liczebności chwastów występujących na polu. Niższą dawkę stosować na chwasty mniej wyrosnięte, we wczesnych fazach rozwojowych i gdy zachwaszczenie jest mniejsze, natomiast wyższą z zalecanych dawek stosować, gdy chwasty są zaawansowane w rozwoju i w przypadku silnego zachwaszczenia.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Pszenica jara, jęczmień jary.

Termin stosowania: środek stosować od fazy 3-4 liści zbóż do początku fazy liścia flagowego zbóż (BBCH 13 – 37).

Maksymalna / zalecana dawka do jednorazowego stosowania: 0,6 l/ha. Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Użytki zielone.

Termin stosowania: środek stosować wiosną lub wczesną jesienią, jednak nie później niż do połowy września, gdy chwasty osiągną wysokość 8-10 cm i wytworzą co najmniej 3-4 liście.

Maksymalna / zalecana dawka do jednorazowego stosowania: 0,8 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Pszenica ozima, pszenżyto ozime, pszenica jara, jęczmień jary, użytki zielone - nie dotyczy

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz): Użytki zielone - 7 dni

1. Na teren potraktowany środkiem nie wpuszczać zwierząt gospodarskich, a szczególnie bydła mlecznego, wcześniej niż po upływie 7 dni od zabiegu.
2. W trakcie zabiegu oraz do 5 dni po zabiegu minimalna temperatura dobową nie powinna być niższa niż 8°C.
3. W przypadku stosowania środka w mieszaninie z innymi herbicydami należy ściśle przestrzegać etykiet tych środków.
4. Środka nie stosować:
 - w zbożach z wsiewką roślin bobowatych (motylkowych),
 - na rośliny słabe lub uszkodzone przez przymrozki, choroby czy szkodniki.
5. Podczas stosowania środka nie dopuścić do:
 - znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w glebie w ciągu okresu wegetacji nie stwarzając zagrożenia dla roślin uprawianych następczo. Po zbiorze roślin uprawnych można uprawiać wszystkie rośliny z wyjątkiem roślin korzeniowych i bulwiastych.

W przypadku wcześniejszego zaorania plantacji potraktowanej środkiem FASHION (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki), po wykonaniu uprawy przedsiewnej na polu tym można uprawiać wszystkie gatunki zbóż jarych i kukurydzę.

~~Na plantacji, na której zastosowano środek FASHION w mieszaninie z innym środkiem ochrony roślin należy uwzględnić działanie następcze innego środka wchodzącego w skład tej mieszaniny.~~

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji, odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin. Użytki zielone (zwierzęta gospodarskie) – 7 dni

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Zboża ozime

BBCH 13: W celu ochrony wód gruntowych produkt stosować co 3 lata na glebach zasadowych i co 2 lata na glebach kwaśnych

BBCH 20: W celu ochrony wód gruntowych stosować ten produkt co 3 lata od BBCH 20 na glebach alkalicznych

BBCH 30: W celu ochrony wód gruntowych nie stosować tego produktu przed BBCH 30 na glebach zasadowych

Zboża jare

BBCH 13: W celu ochrony wód gruntowych stosować ten produkt co 2 lata na glebach zasadowych

BBCH 20: W celu ochrony wód gruntowych stosować ten produkt co 2 lata od BBCH 20 na glebach alkalicznych

BBCH 30: W celu ochrony wód gruntowych nie stosować tego produktu przed BBCH 30 na glebach zasadowych

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w szczelnie zamkniętym pojemniku,
- z dala od źródeł ciepła, iskrzenia, otwartego ognia, gorących powierzchni. Palenie wzbronione. – w temperaturze 0° C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W PRZYPADKU POŁKNIECIA: Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.

NIE wywoływać wymiotów.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not relevant. No letters of Access to protected data is required.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.2.1 KCP 2.2.2 KCP 2.3.3 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.6.1 KCP 2.8.2 KCP 2.7.3 KCP 2.8.2 KCP 2.8.6.1 KCP 2.8.6.2 KCP 2.8.6.3 KCP 2.8.7.2 KCP 2.11	G. B. Azeema	2021	Physico-chemical studies of Fluroxypyr (as Meptyl ester) 250 g a.e./L EC Bioscience Research Foundation Report No.: 9307/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 2.7.1	G. B. Azeema	2021	Accelerated Storage Stability Study of Fluroxypyr (as Meptyl ester) 250 g a.e./L EC Bioscience Research Foundation Report No.: 9308/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1	G. B. Azeema	2021	Physico-chemical studies of Fluroxypyr (as Meptyl ester), Bioscience Research Foundation Report No.: 9307/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 6.2.2-01 <u>Also cited in</u> CP 6.2.1 CP 6.4.1	Stępień, B	2022	The evaluation of efficacy and selectivity of the tested Fluroxypyr 25% EC for the control of weeds in winter wheat Laboratory: GBA Polska Sp z.o.o Trial number: 0026_2022_SHA_D01 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.2.2-02 <u>Also cited in</u> CP 6.2.1 CP 6.4.1	Stępień, B	2022	The evaluation of efficacy and selectivity of the tested Fluroxypyr 25% EC for the control of weeds in winter wheat Laboratory: GBA Polska Sp z.o.o Trial number: 0026_2022_SHA_D02 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.2.2-03 <u>Also cited in</u> CP 6.2.1 CP 6.4.1	Stępień, B	2022	The evaluation of efficacy and selectivity of the tested Fluroxypyr 25% EC for the control of weeds in winter wheat Laboratory: GBA Polska Sp z.o.o Trial number: 0026_2022_SHA_D03 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.2.2-04 <u>Also cited in</u> CP 6.2.1 CP 6.4.1	Stępień, B	2022	The evaluation of efficacy and selectivity of the tested Fluroxypyr 25% EC for the control of weeds in spring barley Laboratory: GBA Polska Sp z.o.o Trial number: 0028_2022_SHA_D01 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2.2-05 <u>Also cited in</u> CP 6.2.1 CP 6.4.1	Stępień, B	2022	The evaluation of efficacy and selectivity of the tested Fluroxypyr 25% EC for the control of weeds in spring barley Laboratory: GBA Polska Sp z.o.o Trial number: 0028_2022_SHA_D02 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.2.2-06 <u>Also cited in</u> CP 6.2.1 CP 6.4.1	Stępień, B	2022	The evaluation of efficacy and selectivity of the tested Fluroxypyr 25% EC for the control of weeds in spring barley Laboratory: GBA Polska Sp z.o.o Trial number: 0028_2022_SHA_D03 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.4.1-01 <u>Also cited in</u> CP 6.4.2	Stępień, B	2022	The evaluation of selectivity of the tested Fluroxypyr 25% EC for the control of weeds in winter wheat Laboratory: GBA Polska Sp z.o.o Trial number: 0027_2022_SHA_D01 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.4.1-02 <u>Also cited in</u> CP 6.4.2	Stępień, B	2022	The evaluation of selectivity of the tested Fluroxypyr 25% EC for the control of weeds in winter wheat Laboratory: GBA Polska Sp z.o.o Trial number: 0027_2022_SHA_D02 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.4.1-03 <u>Also cited in</u> CP 6.4.2	Stępień, B	2022	The evaluation of selectivity of the tested Fluroxypyr 25% EC for the control of weeds in winter wheat Laboratory: GBA Polska Sp z.o.o Trial number: 0027_2022_SHA_D03 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1-04 <u>Also cited in</u> CP 6.4.2	Stępień, B	2022	The evaluation of selectivity of the tested Fluroxypyr 25% EC for the control of weeds in spring barley Laboratory: GBA Polska Sp z.o.o Trial number: 0029_2022_SHA_D01 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.4.1-05 <u>Also cited in</u> CP 6.4.2	Stępień, B	2022	The evaluation of selectivity of the tested Fluroxypyr 25% EC for the control of weeds in spring barley Laboratory: GBA Polska Sp z.o.o Trial number: 0029_2022_SHA_D02 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA
KCP 6.4.1-06 Also cited in CP 6.4.2	Stępień, B	2022	The evaluation of selectivity of the tested Fluroxypyr 25% EC for the control of weeds in spring barley Laboratory: GBA Polska Sp z.o.o Trial number: 0029_2022_SHA_D03 Sharda Reference no.: - GEP, Unpublished	N	Y	Art. 59 (1) (a)&(b) of Regulation 1107/2009 applies	SHA

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner