

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 5**

#### **Analytical Methods**

Detailed summary of the risk assessment

Product code: SHA 5400 A

Product name(s): FASHION

Chemical active substance:

Fluroxypyr, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

**NATIONAL ASSESSMENT**

(authorization)

Applicant: Sharda Cropchem Limited

Submission date: January 2022

Finalisation date: September 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
January 2025	The final Registration Report

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## 5 Analytical methods

### 5.1 Conclusion and summary of assessment

**zRMS conclusion:**

Sufficient analytical methods are available for active substance (Fluroxypyr-1-methyl heptyl ester) and relevant impurity (1-Methyl-2-pyrrolidone) in the plant protection product Fashion.

No data gaps.

The analytical method is validated and meets criteria of specificity, linearity and precision according to the requirements SANCO 3030/99 rev 5, therefore the method is acceptable.

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

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 9<sup>th</sup> 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.

## 5.2 Methods used for the generation of pre-authorization data (KCP 5.1)

### 5.2.1 Analysis of the plant protection product (KCP 5.1.1)

#### 5.2.1.1 Determination of active substance and/or variant in the plant protection product (KCP 5.1.1)

An overview on the acceptable methods and possible data gaps for analysis of Fluroxypyr in plant protection product is provided as follows:

Comments of zRMS:	The analytical method (HPLC-UV) for determination of Fluroxypyr-1-methyl heptyl ester in the formulation Fashion has been submitted. The analytical method is validated and meets criteria of specificity, linearity and precision according to the requirements SANCO 3030/99 rev 5, therefore the method is acceptable.
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Reference:	KCP 5.1.1
Report	Physico-chemical studies of Fluroxypyr (as Meptyl ester), G.B. Azeema, 2021, Report No.: 9307/2021
Guideline(s):	Yes SANCO/3030/99 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

## Materials and methods

### Specificity

#### i. Preparation of Standard Stock Solution

An amount of 10.11 mg Fluroxypyr-1-methylheptyl ester reference standard with purity 98.97% was accurately weighed into a 10 ml volumetric flask, dissolved with Acetonitrile and made upto the mark with Acetonitrile. The concentration of prepared standard (stock-A) solution was equivalent to 1000.59 mg/L.

**ii. Preparation of Standard Stock-B Solution (100.06 mg/L)**

An aliquot of 1.00 ml Standard (stock-A) solution (1000.59 mg/L) was taken into a 10 ml volumetric flask, diluted with Acetonitrile and made upto the mark with the Acetonitrile. The concentration was equivalent to 100.06 mg/L. The prepared standard solution was used for specificity determination.

**iii. Preparation of Sample Solution**

An amount of 100.00 mg of Fluroxypyr (as Meptyl ester) 250 g a.e./l EC was accurately weighed into a clean and dry 100 mL volumetric flask, dissolved in Acetonitrile and made upto the mark with the Acetonitrile. The concentration of prepared stock sample solution was equivalent to 1000.0 mg/L.

**iv. Preparation of Sample Solution (100 mg/L)**

An aliquot of 1.0 ml sample solution (1000 mg/L) was taken into a 10 ml volumetric flask, diluted with Acetonitrile and made upto the mark with the Acetonitrile. The concentration was equivalent to 100 mg/L. The prepared sample solution was used for specificity determination.

The Specificity of HPLC method for Fluroxypyr-1-methylheptyl ester was determined by injecting the standard and sample solutions along with blank. There was no interference observed with the peak of interest. Hence the method was considered to be specific for the analysis of Fluroxypyr (as Meptyl ester).

Linearity

From the standard solutions (1000.59 mg/L - Stock-A) of Fluroxypyr-1-methylheptyl ester, the serial dilutions were made to prepare further concentrations by using Acetonitrile. The details of the dilutions are presented in TABLE 1.

**TABLE 1 DILUTIONS (FLUROXYPYR-1-METHYLHEPTYL ESTER REFERENCE STANDARD)**

Code	Stock Conc. (mg/L)	Aliquot volume (mL)	Final Volume (mL)	Final Conc. (mg/L)	Final Conc. (% w/w)
STD-1	1000.59	0.20	10	20.01	20.01
STD-2	1000.59	0.22	10	22.01	22.01
STD-3	1000.59	0.25	10	25.01	25.01
STD-4	1000.59	0.27	10	27.02	27.02
STD-5	1000.59	0.30	10	30.02	30.02
STD-6	1000.59	0.33	10	33.02	33.02

The linearity of method was established by injecting six different concentrations of Fluroxypyr-1-methylheptyl ester reference standard by HPLC and plotting their respective concentration (mg/L) against the respective peak areas. The Correlation Coefficient (r) was 0.9990 and Coefficient of determination ( $R^2$ ) was 0.9980.

Precision

**i. Preparation of Standard Solution**

The Linearity Standard Solution STD-3 (25.01 mg/L) was used for precision determination.

**ii. Preparation of Sample Solution**

An amount of 67.97 mg, 68.00 mg, 68.10 mg, 68.11 mg and 68.15 mg of Fluroxypyr (as Meptyl ester) 250 g a.e./L EC weighed accurately into a clean and dry 100 ml volumetric flasks separately, dissolved the contents with Acetonitrile and made upto the mark with the Acetonitrile. These solutions were equivalent to 679.7, 680.0, 681.0, 681.1 and 681.5 mg/L respectively.

A volume of 1 ml (679.7, 680.0, 681.0, 681.1 and 681.5 mg/L) sample solutions were taken into a clean

and dry separate 10 ml volumetric flask, diluted with distilled water and made upto the mark with the Acetonitrile. These solutions were were equivalent to 67.97, 68.00, 68.10, 68.11 and 68.15 mg/L respectively.

The bracketing injection of the standard and duplicate injection of five separate preparation of sample concentrations were analyzed under HPLC to determine the relative standard deviation as per Horwitz equation.

Precision was determined by analysing five different sample preparations of Fluroxypyr-1-methylheptyl ester assayed for the quantity of active content in each replication injection. The RSD (%) of the test substance was determined to be 0.0076.

#### Accuracy

The analytical method was validated in terms of recovery of the standard at three fortification levels.

#### **i. Preparation of Standard Solution**

The Linearity Standard Solution STD-3 (25.01 mg/L) was used for recovery determination.

#### **ii. Preparation of Blank Sample Solution**

An amount of 0.55 ml specificity sample stock solution (1000.0 mg/L) was taken into 50 ml volumetric flask, diluted with Acetonitrile and made upto the mark with the Acetonitrile. The concentration was equivalent to 11.00 mg/L. The prepared solution was used for % Recovery determination.

#### **iii. Fortification Level –F1 (20.01 mg/L)**

An aliquot of 0.200 mL standard (Stock-A) solution (1000.59 mg/L) was transferred into a 10 mL volumetric flask and diluted with blank sample solution (11.00 mg/L) and made upto the mark with blank sample solution. This solution was equivalent to 20.01 mg/L.

#### **iv. Fortification Level – F2 (21.01 mg/L)**

An aliquot of 0.210 mL standard (Stock-A) solution (1000.59 mg/L) was transferred into a 10 mL volumetric flask and diluted with blank sample solution (11.00 mg/L) and made upto the mark with blank sample solution. This solution was equivalent to 21.01 mg/L.

#### **v. Fortification Level – F3 (22.01 mg/L)**

An aliquot of 0.220 mL standard (Stock-A) solution (1000.59 mg/L) was transferred into a 10 mL volumetric flask and diluted with blank sample solution (11.00 mg/L) and made upto the mark with blank sample solution. This solution was equivalent to 22.01 mg/L.

The above preparations were analyzed under HPLC by triplicate injections and checked for % recovery.

The accuracy was determined by analyzing the fortified Fluroxypyr-1-methylheptyl ester reference standard in three levels with Fluroxypyr (as Meptyl ester) 250 g a.e./L EC and % recovery was determined by analyzing Fluroxypyr-1-methylheptyl ester at the level F1, F2 and F3. The average accuracy (% Recovery) was F1 – 98.2261%, F2 – 98.0836% and F3 – 99.5330% respectively.

### **Validation - Results and discussions**

**Table 5.2-1: Methods suitable for the determination of active substances Fluroxypyr in plant protection product FASHION/SHA 5400 A**

	<b>Fluroxypyr -1-methyl heptyl ester</b>
<b>Author(s), year</b>	G.B. Azeema, 2021
<b>Principle of method</b>	HPLC -UV

	<b>Fluroxypyr -1-methyl heptyl ester</b>
<b>Linearity</b> (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) $y = 47554x - 17132$ $R^2 = 0.9980$
<b>Precision – Repeatability Mean</b> <b>n = 10</b> (%RSD)	36.0041% w/v %RSD = 0.0076 %RSD <sub>R</sub> = 2.34 %RSD <sub>r</sub> = 1.56 Hr = 0.0049 ≤ 1
<b>Accuracy</b> <b>n = 9</b> (% 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 %
<b>Interference/ Specificity</b>	No intereference: the method is pecific
<b>Comment</b>	-

### Conclusion

According to SANCO/3030/99 rev. 5 the method was successfully validated and is suitable for determination of active substance Fluroxypyr in the test item Fluroxypyr 25% EC.

### 5.2.1.2 Description of analytical methods for the determination of relevant impurities (KCP 5.1.1)

An overview on the acceptable methods and possible data gaps for analysis of relevant impurities in plant protection product is provided as follows:

Comments of zRMS:	The analytical method (HPLC-UV) for determination of 1-Methyl-2-pyrrolidone in the formulation Fashion has been submitted. The analytical method is validated and meets criteria of specificity, linearity and precision according to the requirements SANCO 3030/99 rev 5, therefore the method is acceptable.
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Reference:	KCP 5.1.1
Report	Physico-chemical studies of Fluroxypyr (as Meptyl ester), G.B. Azeema, 2021, Report No.: 9307/2021
Guideline(s):	Yes SANCO/3030/99 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Materials and methods

#### Specificity

##### i. Preparation of Standard (Stock-E) Solution

An amount of 10.12 mg 1-Methyl-2-pyrrolidone reference standard with purity 99.97% was accurately weighed into a 10 ml volumetric flask, dissolved with Acetonitrile and made upto the mark with Acetonitrile. The concentration of prepared standard solution was equivalent to 1010.9880 mg/L.

**ii. Preparation of Standard (Stock-F) Solution (100.09 mg/L)**

An aliquot of 0.99 ml Standard (stock-E) solution (1010.9880 mg/L) was taken into a 10 ml volumetric flask, diluted with Acetonitrile and made upto the mark with the Acetonitrile. The concentration was equivalent to 100.09 mg/L. The prepared standard solution was used for specificity determination.

**iii. Preparation of Sample Solution**

An amount of 100.00 mg of Fluroxyppyr (as Meptyl ester) 250 g a.e./l EC was accurately weighed into a clean and dry 100 mL volumetric flask, dissolved in Acetonitrile and made upto the mark with the Acetonitrile. The concentration of prepared stock sample solution was equivalent to 1000.0 mg/L.

**iv. Preparation of Sample Solution (100 mg/L)**

An aliquot of 1.0 ml sample solution (1000 mg/L) was taken into a 10 ml volumetric flask, diluted with Acetonitrile and made upto the mark with the Acetonitrile. The concentration was equivalent to 100 mg/L. The prepared sample solution was used for specificity determination.

The Specificity of HPLC method for 1-Methyl-2-pyrrolidone was determined by injecting the standard and sample solutions along with blank. There was no interference observed with the peak of interest. Hence the method was considered to be specific for the analysis of 1-Methyl-2-pyrrolidone.

Linearity

From the standard solutions (100.09 mg/L - Stock-F) of 1-Methyl-2-pyrrolidone, the serial dilutions were made to prepare further concentrations by using Acetonitrile. The details of the dilutions are presented in TABLE 1.

**TABLE 1 DILUTIONS (1-METHYL-2-PYRROLIDONE REFERENCE STANDARD)**

Code	Stock Conc. (mg/L)	Aliquot volume (mL)	Final Volume (mL)	Final Conc. (mg/L)	Final Conc. (% w/w)
STD-1	100.09	0.011	10	0.1101	0.1101
STD-2	100.09	0.270	10	2.7024	2.7024
STD-3	100.09	0.340	10	3.4030	3.4031
STD-4	100.09	0.400	10	4.0035	4.0036
STD-5	100.09	0.460	10	4.6040	4.6041
STD-6	100.09	0.520	10	5.2046	5.2047

The linearity of method was established by injecting six different concentrations 1-Methyl-2-pyrrolidone reference standard by HPLC and plotting their respective concentration (mg/L) against the respective peak areas. The Correlation Coefficient (r) was 0.9999 and Coefficient of determination ( $R^2$ ) was 0.99.

Precision

**i. Preparation of Standard Solution**

An aliquot of 0.35 ml Standard (Stock-F) solution (100.09 mg/L) was taken into a 10 ml volumetric flask, diluted with Acetonitrile and made upto the mark with the Acetonitrile. The concentration was equivalent to 3.5032 mg/L. The prepared standard solution was used for precision determination.

**ii. Preparation of Sample Solution**

An amount of 349.9 mg, 350.1 mg, 354.5 mg, 355.2 mg and 355.9 mg of Fluroxypyr (as Meptyl ester) 250 g a.e./L EC weighed accurately into a clean and dry 100 ml volumetric flasks separately, dissolved the contents with Acetonitrile and made upto the mark with the Acetonitrile. These solutions were equivalent to 3499.0, 3501.0, 3545.0, 3552.0 and 3559.0 mg/L respectively.

The bracketing injection of the standard and duplicate injection of five separate preparation of sample concentrations were analyzed under HPLC to determine the relative standard deviation as per Horwitz equation.

Precision was determined by analysing five different sample preparations of 1-Methyl-2-pyrrolidone assayed for the quantity of active content in each replication injection. The RSD (%) of the test substance was determined to be 0.5002.

#### Accuracy

The analytical method was validated in terms of recovery of the standard at three fortification levels.

##### **i. Preparation of Standard Solution**

The Precision Standard Solution (3.5032 mg/L) was used for recovery determination.

##### **ii. Preparation of Blank Sample Solution**

An amount of 10.01 mg of Fluroxypyr (as Meptyl ester) 250 g a.e./L EC was accurately weighted into a clean and dry 100 mL volumetric flask, dissolved in Acetonitrile and made upto the mark with the Acetonitrile. The concentration of prepared blank sample solution was equivalent to 100.1 mg/L.

##### **iii. Fortification Level – F1 (0.1101 mg/L)**

An aliquot of 0.011 mL standard (Stock-F) solution (100.09 mg/L) was transferred into a 10 mL volumetric flask and diluted with blank sample solution (100.1 mg/L) and made upto the mark with blank sample solution. This solution was equivalent to 0.1101 mg/L.

##### **iv. Fortification Level – F2 (2.6023 mg/L)**

An aliquot of 0.260 mL standard (Stock-F) solution (100.09 mg/L) was transferred into a 10 mL volumetric flask and diluted with blank sample solution (100.1 mg/L) and made upto the mark with blank sample solution. This solution was equivalent to 2.6023 mg/L.

##### **v. Fortification Level – F3 (3.3030 mg/L)**

An aliquot of 0.330 mL standard (Stock-F) solution (100.09 mg/L) was transferred into a 10 mL volumetric flask and diluted with blank sample solution (100.1 mg/L) and made upto the mark with blank sample solution. This solution was equivalent to 3.3030 mg/L.

The above preparations were analyzed under HPLC by triplicate injections and checked for % recovery.

The accuracy was determined by analyzing the fortified 1-Methyl-2-pyrrolidone reference standard in three levels with Fluroxypyr (as Meptyl ester) 250 g a.e./L EC and % recovery was determined by analyzing 1-Methyl-2-pyrrolidone at the level F1, F2 and F3. The average accuracy (% Recovery) was F1 – 100.4337%, F2 – 101.2858% and F3 – 99.3261% respectively.

#### Limit of Detection (LOD) and Limit of Quantification (LOQ)

##### **i. Preparation of Standard Solution**

The Precision Standard Solution (3.5032 mg/L) was used for LOD and LOQ determination.

##### **ii. Determination of LOD and LOQ**

The LOD and LOQ were determined by preparing standard solution at estimated LOQ and LOD concentration (based on expected concentration). The solution was injected and analyzed six times. The average response and the standard deviation (SD) of the six results were calculated.

### iii. Preparation of expected lowest concentration of reference standard solution

From the standard (Stock-F) solution (100.09 mg/L) the expected lowest concentration of reference standards were prepared to determine LOD and LOQ. The dilution details and results are presented in TABLE 2.

**TABLE 2 DILUTIONS (LOD & LOQ)**

S.No.	Dilution details			Final concentration (mg/L)
	Concentration (mg/L)	Dilution volume (mL)	Final volume (mL)	
1	100.09	0.011	10	0.1101
2	0.1101	2.300	10	0.0253

The LOD and LOQ were determined based on the lowest concentration response.

LOD is 0.0245 mg/L.

LOQ is 0.1316 mg/L.

### Validation - Results and discussions

**Table 5.2-2: Methods suitable for the determination of the relevant impurities in plant protection product (PPP) FASHION/ SHA 5400 A**

	1-Methyl-2-pyrrolidone
<b>Author(s), year</b>	G.B. Azeema, 2021
<b>Principle of method</b>	HPLC-UV
<b>Linearity (linear between mg/L) (correlation coefficient, expressed as r)</b>	6 points 0.1101 mg/L – 5.2047 mg/L (0.0032 – 0.15% w/v) $y = 9365.3x - 28.394$ $R^2 = 0.9998$
<b>Precision – Repeatability Mean n = 10 (%RSD)</b>	0.0994 % w/v %RSD = 0.5002 %RSD <sub>R</sub> = 5.66 %RSD <sub>r</sub> = 3.79 Hr = 0.131 ≤ 1
<b>Accuracy n = 9 (% Recovery)</b>	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%  Total mean recovery: 100.3485%
<b>Interference/ Specificity</b>	No interference: the method is specific
<b>LOQ</b>	0.1316 mg/L
<b>Comment</b>	-

### Conclusion

According to SANCO/3030/99 rev. 5 the method was successfully validated and is suitable for determination of relevant impurity 1-Methyl-2-pyrrolidone in the test item Fluroxypyr 25% EC.

### 5.2.1.3 Description of analytical methods for the determination of formulants (KCP

### **5.1.1)**

Not relevant.

#### **5.2.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)**

Fluroxypyr CIPAC No.: 431

#### **5.2.2 Methods for the determination of residues (KCP 5.1.2)**

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).

#### **5.3 Methods for post-authorization control and monitoring purposes (KCP 5.2)**

##### **5.3.1 Analysis of the plant protection product (KCP 5.2)**

##### **5.3.2 Description of analytical methods for the determination of residues Fluroxypyr (as Meptyl ester) (KCP 5.2)**

###### **5.3.2.1 Overview of residue definitions and levels for which compliance is required**

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).

###### **5.3.2.2 Description of analytical methods for the determination of residues in plant matrices (KCP 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).

###### **5.3.2.3 Description of analytical methods for the determination of residues in animal matrices (KCP 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).

###### **5.3.2.4 Description of methods for the analysis of soil (KCP 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).

###### **5.3.2.5 Description of methods for the analysis of water (KCP 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).

Data gap:

- Methods (primary and ILV) are required by the REGULATION (EU) No 284/2013 and SAN-TE/2020/12830, Rev.1

#### **5.3.2.6 Description of methods for the analysis of air (KCP 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).

#### **5.3.2.7 Description of methods for the analysis of body fluids and tissues (KCP 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).

Data gap:

- Methods (primary and ILV) are required by the REGULATION (EU) No 284/2013 and SAN-TE/2020/12830, Rev.1

#### **5.3.2.8 Other studies/ information**

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

## Appendix 1 Lists of data considered in support of the evaluation

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	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	Sharda Cropchem Limited

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

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

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

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

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-
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## **Appendix 2 Detailed evaluation of submitted analytical methods**

### **A 2.1 Analytical methods for Fluroxypyr (as Meptyl ester)**

#### **A 2.1.1 Methods used for the generation of pre-authorization data (KCP 5.1)**

No new or additional studies have been submitted

#### **A 2.1.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)**

##### **A 2.1.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.4 Description of Methods for the Analysis of Water (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.5 Description of Methods for the Analysis of Air (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.7 Other Studies/ Information**

No new or additional studies have been submitted