

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 10**

#### **Assessment of the relevance of metabolites in groundwater**

##### **Detailed summary of the risk assessment**

**Product code: SHA 5400 A**

**Product name(s): FASHION**

**Chemical active substance(s):**

**Fluroxypyr, 250 g/L**

**Central Zone**

**Zonal Rapporteur Member State: Poland**

**NATIONAL ASSESSMENT Poland**

**(Authorization)**

**Applicant: Sharda Cropchem Limited**

**Submission date: January 2022**

**MS 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

## Table of Contents

<b>10</b>	<b>Relevance of metabolites in groundwater .....</b>	<b>4</b>
	General information .....	5
10.1	Relevance assessment of metabolite 1 .....	5
10.1.1	STEP 1: Exclusion of degradation products of no concern .....	5
10.1.2	STEP 2: Quantification of potential groundwater contamination.....	5
10.1.3	STEP 3: Hazard assessment – identification of relevant metabolites.....	5
10.1.3.1	STEP 3, Stage 1: screening for biological activity .....	5
10.1.3.2	STEP 3, Stage 2: screening for genotoxicity .....	5
10.1.3.3	STEP 3, Stage 3: screening for toxicity .....	5
10.1.4	STEP 4: Exposure assessment – threshold of concern approach.....	5
10.1.5	STEP 5: Refined risk assessment.....	5
10.2	Relevance assessment of metabolite 2 .....	6
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>7</b>
<b>Appendix 2</b>	<b>Additional information.....</b>	<b>9</b>

## 10 Relevance of metabolites in groundwater

### Introduction

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

Fluroxypyr was renewed and approved under Commission Implementing Regulation (EU) No 736/2011 of 26 July 2011 and was subsequently listed as an approved active substance under Regulation 1107/2009 on 25th May 2011 (Implementing Regulation 540/2011). Data protection on all active substance data submitted on Fluroxypyr expired on 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.

## **General 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).

### **10.1 Relevance assessment of metabolite 1**

#### **10.1.1 STEP 1: Exclusion of degradation products of no concern**

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).

#### **10.1.2 STEP 2: Quantification of potential groundwater contamination**

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).

#### **10.1.3 STEP 3: Hazard assessment – identification of relevant metabolites**

##### **10.1.3.1 STEP 3, Stage 1: screening for biological activity**

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).

##### **10.1.3.2 STEP 3, Stage 2: screening for genotoxicity**

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).

##### **10.1.3.3 STEP 3, Stage 3: screening for toxicity**

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).

#### **10.1.4 STEP 4: Exposure assessment – threshold of concern approach**

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).

#### **10.1.5 STEP 5: Refined risk assessment**

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

## **10.2 Relevance assessment of metabolite 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).

**ACCEPTED**

## 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

### 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>

## **Appendix 2 Additional 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).