

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 5400 A

Product name: FASHION

Chemical active substance:

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; December 2023;

January 2025

Version history

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

Table of Contents

6	Mammalian Toxicology (KCP 7)	4
6.1	Summary	4
6.2	Toxicological Information on Active Substance	5
6.3	Toxicological Evaluation of Plant Protection Product.....	6
6.4	Toxicological Evaluation of Groundwater Metabolites.....	7
6.5	Dermal Absorption (KCP 7.3)	7
6.6	Exposure Assessment of Plant Protection Product (KCP 7.2).....	7
Appendix 1	Lists of data considered in support of the evaluation.....	9
Appendix 2	Detailed evaluation of the studies relied upon.....	10
A 2.1	Statement on bridging possibilities	10
A 2.2	Acute oral toxicity (KCP 7.1.1)	10
A 2.3	Acute percutaneous (dermal) toxicity (KCP 7.1.2)	10
A 2.4	Acute inhalation toxicity (KCP 7.1.3)	11
A 2.5	Skin irritation (KCP 7.1.4).....	11
A 2.6	Eye irritation (KCP 7.1.5).....	11
A 2.7	Skin sensitisation (KCP 7.1.6).....	11
A 2.8	Supplementary studies for combinations of plant protection products (KCP 7.1.7)	12
A 2.9	Data on co-formulants (KCP 7.4)	12
A 2.9.1	Material safety data sheet for each co- formulants.....	12
A 2.9.2	Available toxicological data for each co-formulant.....	12
A 2.10	Studies on dermal absorption (KCP 7.3)	12
A 2.11	Other/Special Studies.....	13
Appendix 3	Exposure calculations	13
A 3.1	Operator exposure calculations (KCP 7.2.1.1)	13
A 3.2	Worker exposure calculations (KCP 7.2.3.1)	13
A 3.3	Bystander and resident exposure calculations (KCP 7.2.2.1).....	13
Appendix 4	Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2. KCP 7.2.1.1. KCP 7.2.2.1. KCP 7.2.3.1)	13

6 Mammalian Toxicology (KCP 7)

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 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.

6.1 Summary

Table 6.1-1: Information on SHA 5400 A/ FASHION *

Product name and code	SHA 5400 A/ FASHION
Formulation type	Emulsion concentrate [Code: EC]
Active substance(s) (incl. content)	Fluroxypyr, 250 g/L

Function	Herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of SHA 5400 A/ FASHION can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for SHA 5400 A/ FASHION according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Skin Irrit. 2, Eye Irrit. 2, Asp.Tox.1 , Carc. 2, STOT SE 3
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07, GHS08
Signal word	Warning -Danger
Hazard statement(s)	H315, H319, H304 , H351, H335, H336
Precautionary statement(s)	P201, P261, P264, P271, P280, P302+P352, P305+P351+P338, 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]

6.2 Toxicological Information on Active Substance

A summary of the toxicological evaluation for SHA 5400 A/ FASHION is given in the following tables. Full summaries of calculations on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.2-1: Summary of acute toxicity calculations including skin irritation and skin sensitization for SHA SHA 5400 A/ FASHION

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	> 2000 mg/kg	Yes	None	Calculated
LD ₅₀ dermal, rat	-	Yes	None	Calculated
LC ₅₀ inhalation, rat	-	Yes	None	Calculated
Skin irritation, rabbit	Irritant	Yes	Skin Irrit. 2; H315	Calculated
Eye irritation, rabbit	Irritant	Yes	Eye Irrit. 2; H319	Calculated
Skin sensitisation, guinea pig	Non-Sensitising	Yes	None	Calculated
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.2-2: Additional toxicological information relevant for classification/labelling of SHA 5400 A/ FASHION

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Fluroxypyr (25% (w/w))	None	Reg. 1272/2008	None
Toxicological properties of non-active substance(s) (relevant for classification of product)	Co-formulant 1 < 10% (w/w)*	H315, H319, H351, H336	Reg. 1272/2008	None
	Co-formulant 2 < 5% (w/w)*	H302, H315, H319, H351	Reg. 1272/2008	H315, H319, H351
	Co-formulant 3 < 1% (w/w)*	H302, H315, H319, H351	Reg. 1272/2008	H315, H319, H351
	Co-formulant 4 > 50% (w/w)*	H304, H335, H336	Reg. 1272/2008	H335, H336
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

** Material safety data sheet by the applicant

6.3 Toxicological Evaluation of Plant Protection Product

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

6.4 Toxicological Evaluation of Groundwater Metabolites

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.

6.5 Dermal Absorption (KCP 7.3)

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.

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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.

6.6.1 Operator exposure (KCP 7.2.1)

6.6.2 Estimation of operator exposure

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.

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.”

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

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.

**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**

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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.

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.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

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

No additional study submitted.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

No additional study submitted.

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

No additional study submitted.

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information
-------------------	---

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p>The acute oral toxicity of SHA 5400 A / FASHION was estimated to be over 2000 mg/kg.</p> <p>Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is not classified. No signal word or hazard statement is required for this hazard.</p>
-------------------	---

Acute toxicity studies for SHA 5400 A / FASHION were **not** evaluated as part of the EU review of Flu-roxypyr. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of SHA 5400 A / FASHION can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute oral toxicity of SHA 5400 A / FASHION was calculated as follow:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$
$$ATE_{mix} = \frac{100}{\frac{xx\%}{900} + \frac{xx\%}{700}} = > 2000 \text{ mg/kg bw}$$

The acute oral toxicity of SHA 5400 A / FASHION was estimated to be over 2000 mg/kg.

Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	<p>According to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is not classified. No signal word or hazard statement is required for this hazard</p>
-------------------	---

There is no co-formulants in the SHA 5400 A / FASHION, classified as toxic to the skin.

Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	According to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is not classified. No signal word or hazard statement is required for this hazard.
-------------------	--

There is no co-formulants in the SHA 5400 A / FASHION, classified as toxic by inhalation.

Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	The product contains $\geq 10\%$ of formulants considered as skin irritant (classified as: Skin Irrit. 2; H315) Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is classified as skin irritant, therefore H315 with pictogram GHS07 and signal word “Warning” is proposed.
-------------------	--

The product contains $\geq 10\%$ of formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008

Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is classified as skin irritant, therefore H315 with pictogram GHS07 and signal word “Warning” is proposed.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	The product contains $\geq 10\%$ of formulants considered as eye irritant (classified as: Eye Irrit. 2; H319). Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is classified as eye irritant, therefore H319 with pictogram GHS07 and signal word “Warning” is proposed. But 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, therefore is not classified
-------------------	--

The product contains $\geq 10\%$ of formulants considered as eye irritant (classified as: Eye Irrit. 2; H319). Under the GHS classification system this component gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008

Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is classified as eye irritant, therefore H319 with pictogram GHS07 and signal word “Warning” is proposed.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	According to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is not classified. No signal word or hazard statement is required for this hazard.
-------------------	--

There is no co-formulants in the SHA 5400 A / FASHION, classified as skin sensitizer.

Therefore, according to the Regulation EC No. 1272/2008, SHA 5400 A / FASHION is **not classified**. No signal word or hazard statement is required for this hazard.

Comments

The FASHION classification was carried out using a calculation method based on the classification of the active substance and inert ingredients see Part C: H315,H319,H335,H336, H351

However, 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

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

Not relevant.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

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

A 2.11 Other/Special Studies

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).Exposure calculations

A 2.12 Operator exposure calculations (KCP 7.2.1.1)

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.

A 2.13 Worker exposure calculations (KCP 7.2.3.1)

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.

A 2.14 Bystander and resident exposure calculations (KCP 7.2.2.1)

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.

Appendix 3 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2. KCP 7.2.1.1. KCP 7.2.2.1. KCP 7.2.3.1)

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.