

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 7**

#### **Metabolism and Residues**

##### **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).
June 2022	Applicant update
September 2023	ZRMs evaluated dRR submitted by Applicant
January 2025	The final Registration Report

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## **7 Metabolism and residue data (KCA section 6)**

### **7.1 Summary and zRMS Conclusion**

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 Fashion 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 <sup>14</sup>C-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 methoxypyridine and the absence of toxicological data on this metabolite).

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

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

#### **7.1.1 Critical GAP(s) and overall conclusion**

**Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)**

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).

<b>zRMS:</b>													
										GAP rev. 0, date: January 2022			
PPP (product name/code):		FASHION / SHA 5400 A				Formulation type:		EC (Emulsion Concentrate)					
Active substance 1:		Fluroxypyr				Conc. of as 1:		250 g/L					
Active substance 2:						Conc. of as 2:							
Safener:		-				Conc. of safener:		-					
Synergist:		-				Conc. of synergist:		-					
Applicant:		Sharda Cropchem Limited				Professional use:		<input checked="" type="checkbox"/>					
Zone(s):		Poland				Non professional use:		<input type="checkbox"/>					
Verified by MS:		yes/no											
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		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													

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 Tribenuron methyl 750 g/Kg Granstar 75 WG 15 g/ha
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 Granstar 75 WG 15 g/ha
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	-	-

## 7.1.2 Summary of the evaluation

### 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.

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

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of Fluroxypyr.**

Reference value	Source	Year	Value	Study relied upon	Safety factor
<b>Fluroxypyr</b>					
ADI	EFSA	2011	0.8 mg/kg bw/day	2-year rat study	100



Reference value	Source	Year	Value	Study relied upon	Safety factor
ARfD	EFSA	2011	Not established, not required.		

## 7.2 Active substance - Fluroxypyr

### 7.2.1.1 Stability of residues in sample extracts (KCA 6.1)

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).

**zRMS:** Fluroxypyr residues stable in wheat matrices (whole plant, straw and grain) over the period of 24 months, when stored frozen at -18°C. Additional studies are not required.

## 7.2.2 Nature of residues in plants, livestock and processed commodities

### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

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).

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

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).

### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

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).

### 7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

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).

#### **zRMS:**

Residue definition for monitoring (plants and animals): Fluroxypyr (sum of fluroxypyr, its salts, its esters, and its conjugates, expressed as fluroxypyr) (Reg. (EU) 2022/1363)

Residue definition for risk assessment (plants and animals): Fluroxypyr, its esters, salts and its conjugates expressed as fluroxypyr (EFSA Journal 2011;9(3):2091)

The residue definition for risk assessment set for the primary crops may also apply to the rotational crops

on a tentative basis but in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite, rotational crops field trials covering the maximum plateau concentration of this metabolite are required. EFSA recommends avoiding rotation with root and tuber crops.

EFSA Journal 2019;17(9):5816 (*Animal residue definition for risk assessment*):

*Residue definition for risk assessment (tentatively derived in the MRL review)*

*Ruminants: sum of fluroxypyr and its salts, expressed as fluroxypyr (tentative) (EFSA, 2013) Poultry: in the context of the MRL review a metabolism study in poultry was submitted but not triggered and therefore no residue definition was proposed for poultry matrices (EFSA, 2013)*

*Residue definition for risk assessment (evaluation of confirmatory data following the MRL review)*

*The tentative residue definition for risk assessment (ruminants) could not be confirmed and should be reconsidered, pending on the data gap for toxicological information on the metabolite fluroxypyr pyridinol and its conjugates.*

#### **7.2.2.5 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)**

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).

**zRMS:** see point 7.2.2.4

### **7.2.3 Magnitude of residues in plants (KCA 6.3)**

#### **7.2.3.1 Summary of European data and new data supporting the intended uses**

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).

#### **7.2.3.2 Conclusion on the magnitude of residues in plants**

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).

**zRMS:**

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

MRLs :

wheat, triticale, oat: 0.1 mg/kg

barley: 0.1 mg/kg

rye: 0.1 mg/kg

Uses are accepted.

## 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

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).

**zRMS:** The requested uses modify the theoretical maximum daily intake for animals. Nevertheless, according to the available data there is no risk for animal MRLs to be exceeded.

Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration).

Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
<b>Risk assessment residue definition:</b> sum of Fluroxypyr, its ester, its salts and its conjugates, expressed as Fluroxypyr					
Cattle (all diets)	0.975	1.515	Grass, forage (fresh)	39.40	Y
Cattle (dairy only)	0.975	1.515	Grass, forage (fresh)	39.40	Y
Sheep (all diets)	1.337	2.078	Grass, forage (fresh)	62.33	Y
Sheep (ewe only)	1.337	2.078	Grass, forage (fresh)	62.33	Y
Swine (all diets)	0.196	0.304	Grass, forage (fresh)	13.17	Y
Poultry (all diets)	0.017	0.027	Wheat straw	0.39	Y
Poultry (layer only)	0.017	0.027	Wheat straw	0.39	Y

### 7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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).

## 7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

### 7.2.5.1 Available data for all crops under consideration

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).

### 7.2.5.2 Conclusion on processing 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).

## 7.2.6 Magnitude of residues in representative succeeding crops

### 7.2.6.1 Field rotational crop studies (KCA 6.6.2)

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).

#### zRMS:

Confined studies conducted with <sup>14</sup>C-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 methoxypyridine and the absence of toxicological data on this metabolite).

### 7.2.7 Other/ special studies (KCA6.10, 6.10.1)

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).

## 7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

### 7.2.8.1 Input values for the consumer 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).

**Table 7.2-1: Input values for the consumer risk assessment**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Fluroxypyr, its esters, salts and its conjugates expressed as fluroxypyr				
Input values for the consumer risk assessment used in PRiMo was MRL values from Reg. (EU) 2021/1098				

### 7.2.8.2 Conclusion on consumer 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).

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-2: 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 Fluroxypyr 25% EC do not represent unacceptable chronic risks for the consumer.

### 7.3 Combined exposure and risk assessment

#### 7.3.1 Acute consumer risk assessment from combined exposure

Not applicable.

#### 7.3.2 Chronic consumer risk assessment from combined exposure

Not applicable.

### 7.4 References

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance fluroxypyr (evaluated variant fluroxypyr-meptyl). EFSA Journal 2011;9(3):2091

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fluroxypyr according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3495

EFSA (European Food Safety Authority), 2019. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review for fluroxypyr. EFSA Journal 2019;17(9):5816.

## 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 and 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 Detailed evaluation of the additional studies relied upon**

### **A 2.1 Active substance Fluroxypyr**

#### **A 2.1.1 Stability of residues**

##### **A 2.1.1.1 Stability of residues during storage of samples**

###### **A 2.1.1.1.1 Storage stability of residues in plant products**

###### **A 2.1.1.1.1.1 Study 1**

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 2.1.1.1.2 Storage stability of residues in animal products**

###### **A 2.1.1.1.2.1 Study 1**

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 2.1.2 Nature of residues in plants, livestock and processed commodities**

#### **A 2.1.2.1 Nature of residue in plants**

##### **A 2.1.2.1.1 Nature of residue in primary crops**

###### **A 2.1.2.1.1.1 Study 1**

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 2.1.2.1.2 Nature of residue in rotational crops**

###### **A 2.1.2.1.2.1 Study 1**

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 2.1.2.1.3      Nature of residues in processed commodities**

#### **A 2.1.2.1.4      Study 1**

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 2.1.3            Magnitude of residues in plants**

#### **A 2.1.3.1          Crop 1**

##### **A 2.1.3.1.1      Study 1**

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 2.1.3.1.2      Study 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).

#### **A 2.1.3.2          Crop 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).

### **A 2.1.4            Magnitude of residues in livestock**

#### **A 2.1.4.1          Livestock feeding studies**

##### **A 2.1.4.1.1      Livestock feeding study 1**

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 2.1.5            Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)**

#### **A 2.1.5.1          Distribution of the residue in peel/pulp**

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 2.1.5.1.1 Study 1**

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 2.1.5.2 Processing studies on a core set of representative processes**

##### **A 2.1.5.2.1 Study 1**

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 2.1.6 Magnitude of residues in representative succeeding crops**

##### **A 2.1.6.1 Study 1**


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 2.1.7 Other/Special Studies**

##### **A 2.1.7.1 Study 1**

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 3.1 TMDI calculations

 European Food Safety Authority		<div> <div>Fluroxypyr</div> <div> <div>LOQs (mg/kg): range from: 0.02 to: 6.10</div> <div>Toxicological reference values</div> </div> </div> <div> <div>ADI (mg/kg bw/day): 0.8</div> <div>ARID (mg/kg bw): -</div> </div> <div> <div>Source of ADI:</div> <div>Year of evaluation:</div> </div>		<div>Input values</div> <div> <div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div> </div> <div> <div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div> </div>							
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
		No. of diets exceeding the ADI: ---									
TMDI/NED/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities under assessment (in % of ADI)	
	0.7%	NL toddler	5.77	0.2%	Maize/corn	0.1%	Milk: Cattle	0.1%	Potatoes	0.3%	
	0.8%	DE child	3.67	0.1%	Potatoes	0.1%	Wheat	0.0%	Milk: Cattle	0.2%	
	0.4%	NL child	2.87	0.1%	Potatoes	0.1%	Milk: Cattle	0.1%	Wheat	0.2%	
	0.4%	GEMS/Food G08	2.81	0.1%	Wheat	0.0%	Potatoes	0.0%	Maize/corn	0.1%	
	0.3%	GEMS/Food G15	2.80	0.1%	Potatoes	0.1%	Wheat	0.0%	Parsley	0.1%	
	0.3%	GEMS/Food G10	2.79	0.1%	Potatoes	0.1%	Parsley	0.0%	Wheat	0.1%	
	0.3%	GEMS/Food G08	2.78	0.1%	Potatoes	0.1%	Wheat	0.0%	Parsley	0.1%	
	0.3%	GEMS/Food G07	2.75	0.1%	Potatoes	0.1%	Wheat	0.0%	Parsley	0.1%	
	0.3%	UK infant	2.64	0.1%	Milk: Cattle	0.1%	Potatoes	0.0%	Wheat	0.1%	
	0.3%	GEMS/Food G11	2.57	0.1%	Potatoes	0.0%	Wheat	0.0%	Milk: Cattle	0.1%	
	0.3%	IE adult	2.54	0.1%	Potatoes	0.0%	Basil and edible flowers	0.0%	Peas	0.1%	
	0.3%	FR child 3-15 yr	2.49	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	Potatoes	0.1%	
	0.3%	FR toddler 2-3 yr	2.47	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.1%	
	0.3%	UK toddler	2.30	0.1%	Potatoes	0.1%	Milk: Cattle	0.0%	Wheat	0.1%	
	0.3%	RO general	2.28	0.1%	Potatoes	0.1%	Wheat	0.0%	Milk: Cattle	0.1%	
	0.3%	DK child	2.26	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat	0.1%	
	0.3%	SE general	2.20	0.1%	Potatoes	0.0%	Wheat	0.0%	Milk: Cattle	0.1%	
	0.3%	PT general	2.06	0.1%	Potatoes	0.0%	Wheat	0.0%	Maize/corn	0.0%	
	0.2%	ES child	1.87	0.1%	Wheat	0.0%	Potatoes	0.0%	Milk: Cattle	0.1%	
	0.2%	FI 3 yr	1.63	0.1%	Potatoes	0.0%	Wheat	0.0%	Rye	0.0%	
	0.2%	NL general	1.58	0.1%	Potatoes	0.0%	Wheat	0.0%	Milk: Cattle	0.1%	
	0.2%	DE women 14-50 yr	1.57	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.1%	
	0.2%	DE general	1.56	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.1%	
	0.2%	FR infant	1.41	0.0%	Potatoes	0.0%	Milk: Cattle	0.0%	Beans (with pods)	0.1%	
	0.2%	IT toddler	1.40	0.1%	Wheat	0.0%	Potatoes	0.0%	Other herbs	0.0%	
	0.2%	FI 6 yr	1.35	0.1%	Potatoes	0.0%	Wheat	0.0%	Peas	0.0%	
	0.1%	LT adult	1.18	0.1%	Potatoes	0.0%	Rye	0.0%	Wheat	0.0%	
	0.1%	FI adult	1.12	0.1%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.1%	
	0.1%	FR adult	1.10	0.0%	Wheat	0.0%	Potatoes	0.0%	Milk: Cattle	0.1%	
	0.1%	ES adult	1.09	0.0%	Wheat	0.0%	Potatoes	0.0%	Milk: Cattle	0.0%	
	0.1%	IT adult	1.09	0.1%	Wheat	0.0%	Other herbs	0.0%	Potatoes	0.0%	
	0.1%	PL general	1.03	0.1%	Potatoes	0.0%	Celery leaves	0.0%	Apples	0.0%	
	0.1%	UK vegetarian	0.96	0.0%	Potatoes	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	
	0.1%	DK adult	0.69	0.0%	Potatoes	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	
	0.1%	UK adult	0.85	0.0%	Potatoes	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	
	0.1%	IE child	0.47	0.							

### **A 3.2 IEDI calculations**

~~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).~~

Not required.

### **A 3.3 IESTI calculations - Raw commodities**

~~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).~~

Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

### **A 3.4 IESTI calculations - Processed commodities**

~~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).~~

Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

## **Appendix 4    Additional information provided by the 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).