

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: FLD-HER 306 SE

Product name(s): KONIK

Chemical active substances:

2,4-D 300 g/L

florasulam 6.25 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: January 2021

MS Finalisation date: 08/2021; 11/2021

Version history

When	What
08/2021	RMS finalised the dRR assessment
11/ 2021	Final Registration Report

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable used conditions required for the registration of FLD-HER 306 SE, containing 2,4-D, 300 g/L and florasulam; 6.25 g/L in Poland. This evaluation is required since the product is a new formulation and has not yet been authorised in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in the Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to FLD-HER 306 where that data has not been considered in the EU review. Otherwise assessments for the safe use of FLD-HER 306 have been made using endpoints agreed in the EU review of 2,4-D and florasulam.

This document describes the specific conditions of use and labelling required for Poland for the registration of FLD-HER 306.

1.1 Application background

This application was submitted by Pestila Spółka z ograniczoną odpowiedzialnością.

This is the application for registration plant protection product under working name of FLD-HER 306 SE according to Article 33 of Regulation 1107/2009. FLD-HER 306 is a suspo-emulsion (SE), containing 6.25 g/L of florasulam and 300 g/L of 2,4-D to be used as a herbicide to protect winter and spring cereals and maize.

1.2 Letters of Access

Letters of Access is submitted. See Appendix 3.

1.3 Justification for submission of tests and studies

Author	Year	Title Report number Source GLP Published	Justification for submitting
Section 1: Identity			
Section 2: Physical and chemical properties,			
Section 4: Further information			
Zajac S.	2019	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k.	Regarding Commission Regulation (EU) No. 284/2013 of 1st of March 2013 it was assess that in case when the new recipe of the generic plant protection product is developed it is necessary to gener-

		GLP Yes Unpublished	ate physical and chemical properties in order to check if it fulfils FAO specification, is safe, stable etc. The range of studies performed for FLD-HER 306 SE are those recommended for SE formulation.
Śliwa P.	2019	FLD-HER 306 SE Determination of explosive properties Report No BW-02/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	
Flasińska P.	2019	FLD-HER 306 SE Determination of flash point, auto-ignition temperature and oxidizing properties. Report No BC-09/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	
Zajac S.	2019	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Stage 3: Determination of physicochemical properties of preparation stored at temperature 54±2°C for 14 days. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	
Arévalo E.	2019	FLD-HER 306 SE Determination of viscosity. Report No BF-17/19-02 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	
Łysik A.	2019	FLD-HER 306 SE Determination of surface tension. Report No BF-17/19-03 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	
Zajac S.	2019	FLD-HER 306 SE. Determination of active substances content of preparation in COEX bottle. Stage 1: Determination of active substances content of initial preparation. Stage 3: Determination of active substances content of preparation stored at temperature 54±2°C for 14 days. Report No 007/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	
Gutowska I.	2019	FLD-HER 306 SE (2,4-D 300 g/L + florasulam 6.25 g/L) Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation. Report No BA-21/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	
Gutowska I.	2020	Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation after the accelerated storage Report No BA-09/20	

		Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished.	
Grodowska K.	2020	Analysis of FLD-HER 306 SE before and after ageing tests to determine content of dioxins and furans. Report No K458/KG Selvita Services Sp. z o.o. GLP Yes Unpublished.	
Zajac S.	2020	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Stage 4: Determination of physicochemical properties of preparation stored at temperature 20±2°C for 1 year. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	
Arévalo E.	2019	FLD-HER 306 SE Application equipment cleaning effectiveness. Report No BF-17/19-01 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	
Section 3: Efficacy Data and Information			
Chermuła Ł.	2018	Efficacy evaluation of FLD-HER 306 SE against broad-leaved weeds in maize; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S18-03531-01 GLP: Yes Published: No	In accordance with the requirements of Commission Regulation (EU) No. 284/2013 of 1st of March 2013 “ <i>The data supplied must be sufficient to permit an evaluation of the plant protection product to be made.</i> ” Recipe for the FLD-HER 306 SE was developed in Pestila Spółka z ograniczoną odpowiedzialnością so it was necessary to confirm efficacy and selectivity.
Chermuła Ł.	2018	Efficacy evaluation of FLD-HER 306 SE against broad-leaved weeds in maize; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S18-03519-01 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02939-01 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02939-02 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02939-03 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize.	

		OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02939-04 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02939-05 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02939-06 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02939-07 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02939-08 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S18-03519-02 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-14 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-15 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-16 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-17 GLP: Yes	

		Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-18 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-19 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-03517-02 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-01 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-02 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-03 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-04 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-05 GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-06	

		GLP: Yes Published: No	
Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02940-07 GLP: Yes Published: No	
Jatczak K.	2019	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in winter wheat. OUTDOOR.2019; Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18055 PL1 F GLP: Yes Published: No	
Jatczak K.	2019	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in spring wheat. OUTDOOR.2019; Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18056 PL2 F GLP: Yes Published: No	
Jatczak K.	2019	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in maize. OUTDOOR.2019; Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18057 PL1 F GLP: Yes Published: No	
Jatczak K.	2019	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in maize. OUTDOOR.2019; Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18057 PL2 F GLP: Yes Published: No	
Katulski B.	2018	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in winter wheat. SGS Polska Sp. z o.o., Poland; Report No.: Pestila_2018—S_001 GLP: Yes Published: No	
Katulski B.	2018	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in spring wheat. SGS Polska Sp. z o.o., Poland; Report No.: Pestila_2018—S_002 GLP: Yes Published: No	
Katulski B.	2018	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in maize. SGS Polska Sp. z o.o., Poland; Report No.: Pestila_2018—S_008 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in maize. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02932-01 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in maize. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02932-02 GLP: Yes	

		Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in maize. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02932-03 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in maize. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02932-04 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-01 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-02 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-03 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-04 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-05 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter triticale. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-11 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter triticale. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-12 GLP: Yes Published: No	
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter triticale. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-13 GLP: Yes Published: No	

Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter triticale. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-14 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter rye. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-15 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter rye. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-16 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter rye. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-17 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter rye. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-18 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring barley. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-20 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring barley. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-21 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring barley. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-22 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring barley. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-23 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-24 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-25 GLP: Yes Published: No

Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-26 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring wheat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-27 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in common oat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-29 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in common oat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-30 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in common oat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-31 GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in common oat. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-32 GLP: Yes Published: No
Jatczak K.	2018	Field study to evaluate the selectivity of FLD-HER 306 SE when applied in winter barley. Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18058 PL1 F GLP: Yes Published: No
Jatczak K.	2018	Field study to evaluate the selectivity of FLD-HER 306 SE when applied in winter barley. Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18058 PL2 F GLP: Yes Published: No
Jatczak K.	2018	Field study to evaluate the selectivity of FLD-HER 306 SE when applied in maize. Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18059 PL1 F GLP: Yes Published: No
Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter barley. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-19 GLP: Yes Published: No

Section 5: Analytical Methods			
Zajac S.	2019	FLD-HER 306 SE. Determination of active substances content in preparation in COEX bottle. Stage 1: Determination of active substances content in initial preparation Report No 007/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	Regarding Regulation 284/2013 of 1st of March 2013 it was assess that in case when the new recipe of the generic plant protection product is developed it is necessary to generate analytical methods for determination of active substances and relevant impurities in the formulation in order to check if it fulfils FAO specification, is safe, stable etc.
Zajac S.	2019	FLD-HER 306 SE. Determination of active substances content in prepa-ration in COEX bottle. Stage 3: Determination of active substances content in preparation stored at temperature 54±2°C for 14 days. Report No 007/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	
Gutowska I.	2019	Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation. Report No BA-21/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	
Gutowska I.	2020	FLD-HER 306 SE 2,4-D 300 g/L + Florasulam 6.25 g/L Determination Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation after accelerate storage. Report No BA-09/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	
Grodowska K.	2020	GC method for determination of dioxins and furans in FLD-HER 306 SE Report No RVM/2020/53 Selvita Services Sp. z o.o. GLP Yes Unpublished	
Pstuś J.	2020	Work Progress Report - Development of analytical method for determination of tetra-through octa-chlorinated dioxins and furans by isotope dilution for analysis in Florasulam/2,4-D formulation. Report No REP_20200311_SSV_MWU_Pestila_dioksyny_i_furany_R01v1 Selvita Services Sp. z o.o. GLP: Y Published: N	
Świstak M.	2019	Validation of analytical method for the determination of test item FLD-HER 306 SE in media for breeding aquatic organisms and in deionized water. Study code: 0005/0067/FA SORBOLAB Research Laboratory LLC, Poznań, Poland GLP: Y Published: N	

Świstak M.	2019	Validation of analytical method for the determination of test item FLD-HER 306 SE in media for breeding aquatic. Study code: 0005/0088/FA SORBOLAB Research Laboratory LLC, Poznań, Poland GLP: Y Published: N	
Świstak M.	2019	Validation of analytical method for the determination of test item FLD-HER 306 SE in 50% sucrose solution. Study code: 0005/0074/FA SORBOLAB Research Laboratory LLC, Poznań, Poland GLP: Y Published: N	
Świstak M.	2019	Validation of analytical method for the determination of test item FLD-HER 306 SE in soil for breeding earthworms (E. Fetida). Study code: 0005/0079/FA SORBOLAB Research Laboratory LLC, Poznań, Poland GLP: Y Published: N	
Section 8: Environmental Fate			
Tabor E.	2020	FLD-HER 306 SE Calculation of predicted environmental concentrations of 2,4-D and florasulam in groundwater using the FOCUS groundwater scenarios (FOCUS PEARL, FOCUS PELMO) Company Report No: EST/4/2020 Source: ESTICON Tabor Sp.j., Poland GLP: N Published: N	Modelling of PEC _{gw} and PEC _{sw} according to EU and national requirements is always required.
Tabor E.	2020	FLD-HER 306 SE Calculation of Predicted Environmental Concentrations of 2,4-S and florasulam in surface water using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/5/2020 Source: ESTICON Tabor Sp.j., Poland GLP: N Published: N	
Section 9: Ecotoxicology			
	1984	Measurement of median lethal dose as a rapid indication of contaminant toxicity to fish Environmental Toxicology and Chemistry, Vol. 3, pp. 243-254, 1984 GLP: N Published: Y	In accordance with the requirements of Commission Regulation (EU) No. 284/2013 of 1st of March 2013 testing of the plant protection product shall be necessary where its toxicity cannot be predicted on the basis of data on the active substance.
Kühn, R. <i>et al.</i>	1989	Results of the harmful effects of selected water pollutants (anilines, phenols, aliphatic compounds) to <i>Daphnia magna</i> Wat. Res. Vol. 23, No. 4, pp. 495-499, 1989 GLP: N Published: Y	
Woźniak A.	2019	<i>Daphnia</i> acute immobilization test according to OECD 202 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0068/E GLP: Y Published: N	
Cowgill, U. <i>et al.</i>	1989	Toxicity of nine benchmark chemicals to <i>Skeletonema costatum</i> , a marine diatom Environmental Toxicology and Chemistry, Vol. 8, pp. 451-455, 1989	

		GLP: N Published: Y	
Woźniak A.	2019	Freshwater algae growth inhibition test according to OECD No 201 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0069/E GLP: Y Published: N	
Woźniak A.	2019	<i>Lemna gibba</i> growth inhibition test according to OECD 221 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0070/E GLP: Y Published: N	
Woźniak A.	2019	Water-sediment <i>Myriophyllum spicatum</i> toxicity test according to OECD 239 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0071/E GLP: Y Published: N	
Orzechowska U.	2019	Honeybees, Acute Oral Toxicity Test according to OECD 213 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0072/E GLP: Y Published: N	
Orzechowska U.	2019	Honeybees, Acute Contact Toxicity Test according to OECD 214 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0073/E GLP: Y Published: N	
Orzechowska U.	2019	Honey Bee, Chronic Oral Toxicity Test according to OECD 245 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0075/E GLP: Y Published: N	
Orzechowska U.	2019	Chronic Toxicity Test for Honey Bee Larvae according to OECD GD 239 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0076/E GLP: Y Published: N	
Kręglewska M.	2019	Extended laboratory test (Tier2) for the impact assessment on the parasitic wasp <i>Aphidius rhopalosiphi</i> ; SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0078/E GLP: Y Published: N	
Kręglewska M.	2019	Extended laboratory test (Tier2) for evaluating the effects on the predatory mites <i>Typhlodromus pyri</i> (Scheuten) SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0077/E GLP: Y Published: N	
Rovetto I.	2019	Effects of FLD-HER 306 SE (florasulam 6.5 g/L + 2,4-D-etexyl 297.5 g/L) on <i>Coccinella septempunctata</i> in the laboratory – Extended laboratory test – Year 2019 SAGEA Centro di Saggio s.r.l. Study code: 1075-1075HSAG19/r GLP: Y Published: N	
Rovetto I.	2019	Effects of FLD-HER 306 SE (florasulam 6.5 g/L + 2,4-D-etexyl 297.5 g/L) on <i>Coccinella septempunctata</i> in the laboratory – Extended laboratory test – Year 2019 SAGEA Centro di Saggio s.r.l. Study code: 1074-1074HSAG19/r GLP: Y Published: N	

Woźniak A.	2019	Earthworm reproduction test according to OECD 222 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0080/E GLP: Y Published: N	
Parma P.	2019	Study of impact on soil microorganisms - nitrogen transformation according OECD 216 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0083/E GLP: Y Published: N	
Parma P.	2019	Seedling emergence and seedling growth test according to OECD 208 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0081/E GLP: Y Published: N	
Parma P.	2019	Vegetative Vigour Test according to OECD 227 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0082/E GLP: Y Published: N	

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	FLD-HER 306 SE
Product name in MS	Please refer to the cover letter.
Authorization number	Not applicable.
Function	Herbicide.
Applicant	Pestila Spółka z ograniczoną odpowiedzialnością
Active substance(s) (incl. content)	Florasulam 6.25 g/L 2,4-D 300 g/L (expressed as acid) (452.4 g/L expressed as 2,4-D EHE)
Formulation type	Suspo-emulsion [SE]
Packaging	0.5L, 1L, 2L, 5L, 10L, 20L bottles, cannisters HDPE/PA (COEX), fHDPE professional
Coformulants of concern for national authorizations	Not applicable.
Restrictions related to identity	Not applicable.
Mandatory tank mixtures	Not applicable.
Recommended tank mixtures	Not applicable.

2.2 Conclusion

The evaluation of the application for FLD-HER 306 SE resulted in the decision to grant the authorization.

Toxicology section:

Classification of FLD-HER 306 SE (KONIK): H302,H332,H317,H318. Not risk for operator, worker and bystander / resident (child & adult- buffer zone 5 m) is acceptable under the conditions of the intended use of FLD-HER 306 SE(KONIK).

2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.


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:	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
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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:	 GHS05 GHS07 GHS09
Signal word:	Danger
Hazard statement(s):	H290 – May be corrosive to metals. H302 - Harmful if swallowed. H332 - Harmful if inhaled. H318 - Causes serious eye damage. H317 - May cause an allergic skin reaction. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P261 - Avoid breathing dust/fume/gas/mist/vapours/ spray.. P264 – Wash hands thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P302+P352 - IF ON SKIN: Wash with plenty of water with soap. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several

	minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P333+P313 - If skin irritation or rash occurs: Get medical advice or attention. P391 - Collect spillage
Additional labelling phrases:	SPe3 - To protect aquatic organisms respect an 5m unsprayed buffer zone of to surface water bodies (spring and winter cereals) and 5m vegetated unsprayed buffer zone of to surface water bodies (maize).

Special rule for labelling of plant protection product (PPP):

EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH208	Contains 2,4-D 2EHE (CAS No. 1928-43-4). May produce an allergic reaction.

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

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

SP1	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).
SPe3	To protect aquatic organisms respect an 5m unsprayed buffer zone of to surface water bodies (spring and winter cereals).
SPe3	To protect aquatic organisms respect an 5m vegetated unsprayed buffer zone of to surface water bodies (maize).

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

-	"After the application of product, place warning boards in visible places around the field: "No unauthorized access to the area treated with plant protection products". The boards should remain until the plants are harvested."
-	"During spraying, a protection zone of at least 5m away from residential buildings/habitats and bystanders should be used."

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:	
-	Work wear (arms, body and legs covered) and protective gloves during mixing/loading and during application.
Worker protection:	
-	Work wear (arms, body and legs covered). Protective gloves are recommended.

Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SP1	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).
SPe3	To protect aquatic organisms respect an 5m unsprayed buffer zone of to surface water bodies (spring and winter cereals).
SPe3	To protect aquatic organisms respect an 5m vegetated unsprayed buffer zone of to surface water bodies (maize).
Other specific restrictions	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
-	"After the application of product, place warning boards in visible places around the field: "No unauthorized access to the area treated with plant protection products". The boards should remain until the plants are harvested."
-	"During spraying, a protection zone of at least 5 m away from residential buildings/habitats and bystanders should be used."

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.
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).	1, 2, 3
SPe3	To protect aquatic organisms respect an 5m unsprayed buffer zone of to surface water bodies (spring and winter cereals).	1, 2
SPe3	To protect aquatic organisms respect an 5m vegetated unsprayed buffer zone of to surface water bodies (maize).	3

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	FLD-HER 306 SE	Formulation type:	SE ^(a, b)
Active substance 1:	2,4-D	Conc. of as 1:	300 ^(c)
Active substance 2:	florasulam	Conc. of as 2:	6.25 ^(c)
Active substance....:	-	Conc. of as:	-
Safener:	n.a.	Conc. of safener:	n.a. ^(c)
Synergist:	n.a.	Conc. of synergist:	n.a. ^(c)
Applicant:	Pestila Spółka z ograniczoną odpowiedzialnością	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central Zone ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		

GAP rev. 1, date: 2021-01-01

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, G, Gnp or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	PL	Spring wheat Spring triticale Spring barley Oat	F	Susceptible weeds at rate 0.4 L/ha: CENCY - <i>Centaurea cyanus</i> (Cornflower) CAPBP - <i>Capsella bursa-pastoris</i> (Shep- herd's-purse) ANTAR - <i>Anthemis arvensis</i> (Corn chamo- mile) GALAP - <i>Galium aparine</i> (cleavers) THLAR - <i>Thlaspi arvense</i> (field pennycress) PAPRH - <i>Papaver rhoeas</i> (common poppy) CHEAL - <i>Chenopodium album</i> (fat-hen) AMARE - <i>Amaranthus retroflexus</i> (redroot pigweed) MATIN - <i>Matricaria inodora</i> (scentless false mayweed) STEME - <i>Stellaria media</i> (common chick-	spraying	<u>Spring</u> BBCH 12-32	1	n.a	<u>Spring</u> 0.4-0.6 L/ha	<u>Spring</u> 2.5-3.75 g florasulam 120-180 g 2,4-D	200-300 L/ha	not relevant	not relevant Efficacy section: Spring tritica- le is not accepted

				<p>weed)</p> <p><u>Susceptible weeds at rate 0.6 L/ha:</u> STEME – <i>Stellaria media</i> (common chick-weed) CENCY - <i>Centaurea cyanus</i> (Cornflower) CAPBP - <i>Capsella bursa-pastoris</i> (Shepherd's-purse) ANTAR - <i>Anthemis arvensis</i> (Corn chamomile) GALAP - <i>Galium aparine</i> (cleavers) MATIN - <i>Matricaria inodora</i> (scentless false mayweed) THLAR - <i>Thlaspi arvense</i> (field pennycress) PAPRH - <i>Papaver rhoeas</i> (common poppy) CHEAL - <i>Chenopodium album</i> (fat-hen) AMARE – <i>Amaranthus retroflexus</i> (redroot pigweed)</p> <p><u>Moderately susceptible weeds at rate 0.4 L/ha:</u> LAMAM - <i>Lamium amplexicaule</i> (henbit deadnettle) STEME – <i>Stellaria media</i> (common chick-weed) MATIN - <i>Matricaria inodora</i> (scentless false mayweed) POLCO - <i>Fallopia convolvulus</i> (wild buckwheat)</p> <p><u>Moderately susceptible weeds at rate 0.6 L/ha:</u> LAMAM - <i>Lamium amplexicaule</i> (henbit deadnettle) POLCO - <i>Fallopia convolvulus</i> (wild buckwheat)</p> <p><u>Moderately tolerant weeds at rate 0.6 L/ha</u> VIOAR – <i>Viola arvensis</i> (field pansy) VERHE - <i>Veronica hederifolia</i> (ivy-leaved speedwell)</p> <p><u>Tolerant weeds at rate 0.6 0.4 L/ha:</u> VIOAR – <i>Viola arvensis</i> (field pansy) VERHE - <i>Veronica hederifolia</i> (ivy-leaved speedwell)</p>									
2	PL	Winter wheat Winter triticale Winter barley Rye	F	<p><u>Susceptible weeds at rate 0.4 L/ha:</u> LAMAM - <i>Lamium amplexicaule</i> (henbit deadnettle) LAMPU – <i>Lamium purpureum</i> (purple deadnettle) STEME – <i>Stellaria media</i> (common chickweed) CENCY – <i>Centaurea cyanus</i> (Cornflower) CAPBP - <i>Capsella bursa-pastoris</i> (Shepherd's-purse) ANTAR - <i>Anthemis arvensis</i> (Corn chamomile)</p>	spraying	Spring BBCH 21-32	1	n.a	Spring 0.4-0.6 L/ha	Spring 2.5-3.75 g florasulam 120-180 g 2,4-D	200-300 L/ha	not relevant	not relevant

				<p>GALAP - <i>Galium aparine</i> (cleavers)</p> <p>MATIN - <i>Matricaria inodora</i> (scentless false mayweed)</p> <p>THLAR - <i>Thlaspi arvense</i> (field pennycress)</p> <p>PAPRH - <i>Papaver rhoeas</i> (common poppy)</p> <p>MYOAR - <i>Myosotis arvensis</i> (field forget-me-not)</p> <p><u>Susceptible weeds at rate 0.6 L/ha:</u></p> <p>LAMAM - <i>Lamium amplexicaule</i> (henbit deadnettle)</p> <p>LAMPU - <i>Lamium purpureum</i> (purple deadnettle)</p> <p>STEME – <i>Stellaria media</i> (common chickweed)</p> <p>CENCY - <i>Centaurea cyanus</i> (Cornflower)</p> <p>CAPBP - <i>Capsella bursa-pastoris</i> (Shepherd's-purse)</p> <p>ANTAR - <i>Anthemis arvensis</i> (Corn chamomile)</p> <p>GALAP - <i>Galium aparine</i> (cleavers)</p> <p>MATIN - <i>Matricaria inodora</i> (scentless false mayweed)</p> <p>THLAR - <i>Thlaspi arvense</i> (field pennycress)</p> <p>PAPRH - <i>Papaver rhoeas</i> (common poppy)</p> <p>MYOAR - <i>Myosotis arvensis</i> (field forget-me-not)</p> <p><u>Moderately susceptible weeds at rate 0.4 L/ha:</u></p> <p>FUMOF - <i>Fumaria officinalis</i> (common fumitory)</p> <p>GERPU – <i>Geranium pusillum</i> (small-flower geranium)</p> <p>VERHE - <i>Veronica hederifolia</i> (ivy-leaved speedwell)</p> <p>LAMPU - <i>Lamium purpureum</i> (purple deadnettle)</p> <p>CENCY - <i>Centaurea cyanus</i> (Cornflower)</p> <p><u>Moderately susceptible weeds at rate 0.6 L/ha:</u></p> <p>FUMOF - <i>Fumaria officinalis</i> (common fumitory)</p> <p>GERPU – <i>Geranium pusillum</i> (small-flower geranium)</p> <p>VIOAR – <i>Viola arvensis</i> (field pansy)</p> <p>VERHE - <i>Veronica hederifolia</i> (ivy-leaved speedwell)</p> <p>VERPE - <i>Veronica persica</i> (bird's-eye speedwell)</p> <p><u>Moderately tolerant weeds at 0.4 L/ha:</u></p> <p>VIOAR – <i>Viola arvensis</i> (field pansy)</p> <p>VERPE - <i>Veronica persica</i> (bird's-eye speedwell)</p> <p><u>Moderately Tolerant weeds at rate 0.6 L/ha:</u></p>							
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				<p>VERTR - <i>Veronica triphyllos</i> (fingered speedwell)</p> <p>Tolerant weeds at rate 0,4 L/ha: VERPE – <i>Veronica persica</i> (bird's-eye speedwell) VERTR - <i>Veronica triphyllos</i> (fingered speedwell) VIOAR – <i>Viola arvensis</i> (field pansy)</p> <p>Tolerant weeds at 0,6 L/ha: VERTR – <i>Veronica triphyllos</i> (fingered speedwell)</p>									
3	PL	Maize	F	<p>Susceptible weeds at rate 0.4 L/ha: CHEAL - <i>Chenopodium album</i> (fat-hen) AMARE – <i>Amaranthus retroflexus</i> (redroot pigweed) STEME – <i>Stellaria media</i> (common chick-weed) CENCY - <i>Centaurea cyanus</i> (Cornflower) CAPBP - <i>Capsella bursa-pastoris</i> (Shepherd's-purse) ANTAR - <i>Anthemis arvensis</i> (Corn chamomile) GALAP - <i>Galium aparine</i> (cleavers) MATIN - <i>Matricaria inodora</i> (scentless false mayweed) THLAR - <i>Thlaspi arvense</i> (field pennycress) PAPRH - <i>Papaver rhoeas</i> (common poppy)</p> <p>Susceptible weeds at rate 0.6 L/ha: CHEAL - <i>Chenopodium album</i> (fat-hen) AMARE – <i>Amaranthus retroflexus</i> (redroot pigweed) STEME – <i>Stellaria media</i> (common chick-weed) CENCY - <i>Centaurea cyanus</i> (Cornflower) CAPBP - <i>Capsella bursa-pastoris</i> (Shepherd's-purse) ANTAR - <i>Anthemis arvensis</i> (Corn chamomile) GALAP - <i>Galium aparine</i> (cleavers) POLCO - <i>Fallopia convolvulus</i> (wild buckwheat) MATIN - <i>Matricaria inodora</i> (scentless false mayweed) THLAR - <i>Thlaspi arvense</i> (field pennycress) PAPRH - <i>Papaver rhoeas</i> (common poppy) GERPU - <i>Geranium pusillum</i> (small-flower geranium) POLAV - <i>Polygonum aviculare</i> (prostrate knotweed) SOLNI – <i>Solanum nigrum</i> (black nightshade) LAMAM - <i>Lamium amplexicaule</i> (henbit deadnettel)</p> <p>Moderately susceptible weeds at rate 0.4 L/ha:</p>	spraying	Spring BBCH 12-16	1	n.a.	Spring 0.4-0.6 L/ha	Spring 2.5-3.75 g florasulam 120-180 g 2,4-D	200-300 L/ha	not relevant	not relevant

			<p>LAMAM - <i>Lamium amplexicaule</i> (henbit deadnettel) GERPU - <i>Geranium pusillum</i> (small-flower geranium) POLAV - <i>Polygonum aviculare</i> (prostrate knotweed) SOLNI – <i>Solanum nigrum</i> (black nightshade) VERHE - <i>Veronica hederifolia</i> (ivy-leaved speedwell)</p> <p><u>Moderately susceptible weeds at rate 0.6 L/ha:</u> VIOAR – <i>Viola arvensis</i> (field pansy) VERHE - <i>Veronica hederifolia</i> (ivy-leaved speedwell)</p> <p><u>Moderately Tolerant weeds at rate 0.4 L/ha:</u> POLCO - <i>Fallopia convolvulus</i> (wild buckwheat) VIOAR – <i>Viola arvensis</i> (field pansy)</p>									
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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

- (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.

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.

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 ap-
plication
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)

All studies 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 white to beige liquid, with a specific odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 440 °C. In aqueous solution, it has a pH value around 3,7 at 20 °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.

The stability data indicate a shelf life of at least 1 year at ambient temperature when stored in HDPE/PA (COEX).

Based on 1-year storage stability study shelf life in Poland is: 1 year

Its technical characteristics are acceptable for a SE formulation.

The intended concentration of use is 0,1% to 0,3%.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

No results of the preliminary range-finding tests are presented since no screening trials were carried out. However, the active substances of FLD-HER 306 SE, namely florasulam and 2,4-D, have been commonly used in agricultural practice for many years.

Minimum effective dose tests were not carried out. However, several doses of FLD-HER 306 SE were tested during efficacy studies and the lowest effective dose was selected. The tests were concluded in line with EPPO standard PP 1/225 (2) '*Minimum effective dose*', which advises on the minimum requirements necessary to ensure consistency of decision making.

The applicant carried out efficacy and selectivity trials on winter wheat, spring wheat and maize in Poland in 2018-2019 (for more information please refer to Part B, Section 3 Efficacy Data and Information). Nevertheless, it is possible to use extrapolation tables, according to Polish guidelines. Therefore, the applicant applies for the aforementioned crops to be registered in Poland, namely: spring wheat, spring triticale, spring barley, oat, winter wheat, winter triticale, winter barley, rye and maize. Required selectivity trials have been presented in Part B, Section 3 Efficacy Data and Information.

Efficacy assessment:

All details about efficacy methodology used during 32 efficacy trials are presented above by Applicant. The trials were performed in North-East EPPO zone in Poland in varied soil, environmental and climatic conditions with the use of different agricultural practice.

The experiment was established on a set of complete randomized blocks in 4 replications, statistical methods and observation dates were applied. The reports 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. Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products and are officially GEP recognized. Studies were carried out in 2018 and 2019. The number of efficacy trials of the product presented in this dossier is in accordance with the basic number of trials defined in

EPPO PP/226 (6–15 trials) for N-E for winter wheat (10 trials), spring wheat (10 trials) and maize (12 trials). Also, it is possible to use extrapolation tables, according to Polish guidelines (required selectivity trials for each cereal were submitted by Applicant). Therefore, in Polish label can be registered following crops: winter wheat (on the basis on 10 eff. and 5 sel. trials), spring wheat (on the basis on 10 eff. and 4 sel. trials), spring barley (extrapolation eff. results from spring wheat; 4 sel. trials were submitted), oat (extrapolation eff. results from spring wheat; 4 sel. trials were submitted), winter triticale (extrapolation eff. results from winter wheat; 4 sel. trials were submitted), winter barley (extrapolation eff. results from winter wheat; 3 sel. trials were submitted), rye (extrapolation eff. results from winter wheat; 4 sel. trials were submitted) and maize (on the basis on 12 eff. and 5 sel. trials). Spring triticale should be excluded from GAP table and label project due to lack of efficacy and selectivity trials (at least 2-3 selectivity trials are required).

We are dealing with the active substances used commonly for many years in many countries. In the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations. Minimal level of infestation should be at least 5%.

For Poland applied the scale of efficacy/susceptibility weeds should be due to existing Member State requirements for expressing levels of control for weeds and the practice of preparations by Polish farmers:

- S (susceptible) > 85%
- MS (moderately susceptible) 70-85%
- MT (moderately tolerant) 60-70%
- T (tolerant) < 60%.

The evaluation was conducted in accordance with Uniform Principles. Applicant presented all necessary information's about methodology of efficacy trials above. In all trials standard reference product was used (Mustang 306 SE) with the same active compounds (2,4-D and florasulam). Standard was used at dose 0,6 l/ha.

Applicant correctly presented results. Following weed species were studied during trials (only those weeds for which at least two studies have been performed):

Winter wheat:

- **ANTAR** – 5 trials – number of trials is sufficient. It can be concluded that ANTAR is a susceptible weed at dose 0,4 l/ha (86,2%) and 0,6 l/ha (90,2%).
- **CAPBP** – 6 trials – number of trials is sufficient. It can be concluded that CAPBP is a susceptible weed at dose 0,4 l/ha (88,9%) and 0,6 l/ha (92,3%)
- **CENCY** – 6 trials – number of trials is sufficient. It can be concluded that CENCY is a moderately susceptible weed at dose 0,4 l/ha (84,7%) and susceptible at dose 0,6 l/ha (91,1%).
- **FUMOF** – 2 trials – number of trials is sufficient. It can be concluded that FUMOF is a moderately weed at dose 0,4 l/ha (80,5%) and 0,6 l/ha (83,0%).
- **GALAP** – 6 trials – number of trials is sufficient. It can be concluded that GALAP is a susceptible weed at dose 0,4 l/ha (87,5%) and 0,6 l/ha (89,7%).
- **GERPU** – 2 trials – number of trials is sufficient. It can be concluded that GERPU is a moderately susceptible weed at dose 0,4 l/ha (83,0%) and 0,6 l/ha (84,0%).
- **LAMAM** – 5 trials – number of trials is acceptable. It can be concluded that LAMAM is a susceptible weed at dose 0,4 l/ha (87,2%) and 0,6 l/ha (91,6%).
- **LAMPU** – 2 trials – number of trials is acceptable. It can be concluded that LAMPU is a moderately susceptible weed at dose 0,4 l/ha (84,9%) and susceptible at dose 0,6 l/ha (90,2%).
- **MATIN** – 8 trials – number of trials is sufficient. It can be concluded that MATIN is a susceptible weed at dose 0,4 l/ha (86,9%) and 0,6 l/ha (86,9%).
- **MYOAR** – 5 trials – number of trials is acceptable. It can be concluded that MYOAR is a susceptible weed at dose 0,4 l/ha (86,5%) and 0,6 l/ha (92,7%).

- **PAPRH** – 9 trials – number of trials is acceptable. It can be concluded that PAPRH is a susceptible weed at dose 0,4 l/ha (87,3%) and 0,6 l/ha (91,0%).
- **STEME** – 9 trials – number of trials is sufficient. It can be concluded that STEME is a susceptible weed at dose 0,4 l/ha (89,1%) and 0,6 l/ha (93,6%).
- **THLAR** – 4 trials – number of trials is sufficient. It can be concluded that THLAR is a susceptible weed at dose 0,4 l/ha (87,3%) and 0,6 l/ha (91,8%).
- **VERHE** – 7 trials – number of trials is acceptable. It can be concluded that VERHE is a moderately susceptible weed at dose 0,4 l/ha (70,0%) and 0,6 l/ha (76,0%).
- **VERPE** – 2 trials – number of trials is acceptable. It can be concluded that VERPE is a moderately tolerant weed at dose 0,4 l/ha (66,5%) and moderately susceptible at dose 0,6 l/ha (84,5%).
- **VERTR** – 2 trials – number of trials is sufficient. It can be concluded that VERTR is a tolerant weed at dose 0,4 l/ha (51,5%) and moderately tolerant at dose 0,6 l/ha (69,3%).
- **VIOAR** – 7 trials – number of trials is sufficient. It can be concluded that VIOAR is a moderately tolerant weed at dose 0,4 l/ha (67,7%) and moderately susceptible at dose 0,6 l/ha (76,6%).

Spring wheat:

- **AMARE** – 5 trials – number of trials is acceptable. It can be concluded that AMARE is a susceptible weed at dose 0,4 l/ha (85,6%) and 0,6 l/ha (90,2%).
- **ANTAR** – 4 trials – number of trials is acceptable. It can be concluded that ANTAR is a susceptible weed at dose 0,4 l/ha (85,0%) and 0,6 l/ha (88,3%).
- **CAPBP** – 7 trials – number of trials is sufficient. It can be concluded that CAPBP is a susceptible weed at dose 0,4 l/ha (85,3%) and 0,6 l/ha (89,3%).
- **CENCY** – 5 trials – number of trials is sufficient. It can be concluded that CENCY is a susceptible weed at dose 0,4 l/ha (88,2%) and 0,6 l/ha (89,4%).
- **CHEAL** – 9 trials – number of trials is acceptable. It can be concluded that CHEAL is a susceptible weed at dose 0,4 l/ha (85,3%) and 0,6 l/ha (89,3%).
- **GALAP** – 6 trials – number of trials is acceptable. It can be concluded that GALAP is a susceptible weed at dose 0,4 l/ha (87,8%) and 0,6 l/ha (91,2%).
- **LAMAM** – 3 trials – number of trials is sufficient. It can be concluded that LAMAM is a moderately susceptible weed at dose 0,4 l/ha (77,4%) and 0,6 l/ha (83,6%).
- **MATIN** – 7 trials – number of trials is sufficient. It can be concluded that MATIN is a moderately susceptible weed at dose 0,4 l/ha (84,5%) and susceptible at dose 0,6 l/ha (90,2%).
- **PAPRH** – 4 trials – number of trials is acceptable. It can be concluded that PAPRH is a susceptible weed at dose 0,4 l/ha (85,3%) and 0,6 l/ha (88,3%).
- **POLCO** – 4 trials – number of trials is acceptable. It can be concluded that POLCO is a moderately susceptible weed at dose 0,4 l/ha (75,5%) and 0,6 l/ha (81,1%).
- **STEME** – 5 trials – number of trials is sufficient. It can be concluded that STEME is a susceptible weed at dose 0,4 l/ha (86,8%) and 0,6 l/ha (92,4%).
- **THLAR** – 5 trials – number of trials is sufficient. It can be concluded that THLAR is a susceptible weed at dose 0,4 l/ha (88,0%) and 0,6 l/ha (91,4%).
- **VERHE** – 5 trials – number of trials is acceptable. It can be concluded that VERHE is a tolerant weed at dose 0,4 l/ha (57,2%) and moderately tolerant at dose 0,6 l/ha (61,8%).
- **VIOAR** – 5 trials – number of trials is acceptable. It can be concluded that VIOAR is a tolerant weed at dose 0,4 l/ha (60,0%) and moderately tolerant at dose 0,6 l/ha (66,7%).

Maize:

- **AMARE** – 6 trials – number of trials is sufficient. It can be concluded that AMARE is a susceptible weed at dose 0,4 l/ha (91,3%) and 0,6 l/ha (95,1%).
- **ANTAR** – 4 trials – number of trials is sufficient. It can be concluded that ANTAR is a susceptible weed at dose 0,4 l/ha (88,0%) and 0,6 l/ha (95,8%).
- **CAPBP** – 7 trials – number of trials is acceptable. It can be concluded that CAPBP is a susceptible weed at dose 0,4 l/ha (88,6%) and 0,6 l/ha (93,6%).
- **CENCY** – 4 trials – number of trials is acceptable. It can be concluded that CENCY is a susceptible weed at dose 0,4 l/ha (85,0%) and 0,6 l/ha (90,5%).
- **CHEAL** – 11 trials – number of trials is sufficient. It can be concluded that CHEAL is a susceptible weed at dose 0,4 l/ha (87,2%) and 0,6 l/ha (95,1%).
- **GALAP** – 8 trials – number of trials is sufficient. It can be concluded that GALAP is a susceptible weed at dose 0,4 l/ha (88,0%) and 0,6 l/ha (94,4%).
- **GERPU** – 2 trials – number of trials is acceptable. It can be concluded that GERPU is a moderately susceptible weed at dose 0,4 l/ha (83,2%) and susceptible at dose 0,6 l/ha (91,2%).
- **LAMAM** – 3 trials – number of trials is acceptable. It can be concluded that LAMAM is a moderately susceptible weed at dose 0,4 l/ha (74,0%) and susceptible at dose 0,6 l/ha (86,7%).
- **MATIN** – 6 trials – number of trials is sufficient. It can be concluded that MATIN is a susceptible weed at dose 0,4 l/ha (86,4%) and 0,6 l/ha (94,6%).
- **PAPRH** – 2 trials – number of trials is sufficient. It can be concluded that PAPRH is a susceptible weed at dose 0,4 l/ha (86,0%) and 0,6 l/ha (93,0%).
- **POLAV** – 2 trials – number of trials is acceptable. It can be concluded that POLAV is a moderately susceptible weed at dose 0,4 l/ha (75,9%) and susceptible weed at dose 0,6 l/ha (87,4%).
- **POLCO** – 6 trials – number of trials is acceptable. It can be concluded that POLCO is a moderately tolerant weed at dose 0,4 l/ha (64,7%) and susceptible at dose 0,6 l/ha (87,3%).
- **SOLNI** – 2 trials – number of trials is not sufficient. SOLNI is a major weed in maize so at least 4 valid trials are required. In the opinion of Evaluator, SOLNI should be excluded from GAP table and label project.
- **STEME** – 8 trials – number of trials is acceptable. It can be concluded that STEME is a susceptible weed at dose 0,4 l/ha (85,3%) and 0,6 l/ha (94,0%).
- **THLAR** – 5 trials – number of trials is acceptable. It can be concluded that THLAR is a susceptible weed at dose 0,4 l/ha (86,4%) and 0,6 l/ha (91,7%).
- **VERHE** – 2 trials – number of trials is sufficient. It can be concluded that VERHE is a moderately susceptible weed at dose 0,4 l/ha (75,8%) and 0,6 l/ha (80,8%).
- **VIOAR** – 4 trials – number of trials is sufficient. It can be concluded that VIOAR is a moderately tolerant weed at dose 0,4 l/ha (60,3%) and moderately susceptible at dose 0,6 l/ha (74,8%).

Based on the summarized data, it is therefore considered that claims for control of weeds in maize and cereals (winter and spring) by Konik 306 SE (product code: FLD-HER 306 SE) applied at rate 0,4-0,6 L product/ha and according to other label recommendations, are fully supported. Higher dose should be used only in case of higher infestation.

In Polish label following weeds species can be included for dose 0,4 l/ha as (in brackets the average effectiveness for all tested crops is given):

- *Susceptible:* ANTAR (86,4%), CAPBP (87,6%), CENCY (86,0%), GALAP (87,8%), MATIN (85,9%), MYOAR (86,5%), PAPRH (86,2%), STEME (87,1%), THLAR (87,2%), AMARE (88,5%), CHEAL (86,3%)

- *Moderately susceptible:* FUMOF (80,5%), GERPU (83,1%), LAMAM (79,5%), LAMPU (84,9%), POLCO (70,1%), POLAV (75,9%)
- *Moderately tolerant:* VERHE (67,7%), VERPE (66,5%), VIOAR (62,7%)
- *Tolerant:* VERTR (51,5%).

In Polish label following weeds species can be included for dose 0,6 l/ha as (in brackets the average effectiveness for all tested crops is given):

- *Susceptible:* ANTAR (91,4%), CAPBP (91,7%), CENCY (90,3%), GALAP (91,8%), GERPU (87,6%), LAMAM (87,3%), LAMPU (90,2%), MATIN (90,6%), MYOAR (92,7%), PAPRH (90,8%), STEME (93,3%), THLAR (91,6%), AMARE (92,7%), CHEAL (92,2%)
- *Moderately susceptible:* FUMOF (83,0%), VERHE (72,9%), VERPE (84,5%), VIOAR (72,7%), POLCO (84,2%), POLAV (87,4%)

Moderately tolerant: VERTR (69,3%).

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

According to the HRAC code list and WSSA list active substances of FLD-HER 306 SE represent different modes of action and different levels of the risk of developing herbicide resistant weeds.

FLORASULAM:

Florasulam is a sulfonylurea compound, classified in the HRAC mode of action group B (ALS inhibitors) for which the mode of action involves inhibition of the enzyme acetolactate synthase (ALS). Florasulam belongs to the chemical family triazolopyrimidine, which includes cloransulam-methyl, diclosulam, flumetsulam, metosulam and penoxsulam.

Sulfonylurea herbicides are composed of both an aromatic and a heterocyclic component that are connected by a sulfonylurea bridge.

Florasulam is a selective systemic herbicide taken up by both foliage and roots. Florasulam is non-persistent in the soil with DT₅₀ range 0.58-4.29 days (lab) or 2-18 days (field).

For all groups of herbicides, based on mode of action, cases of resistance occurring in the field worldwide are reported to a specialist herbicide resistance action group and the details recorded on an internet database at www.weedscience.org.

Since the introduction of the first sulfonylurea herbicides in the early 1980s, and with the subsequent introduction of further HRAC mode of action group B (ALS inhibitors) active substances there has been a steady increase in the number of resistant biotypes, with reported cases of resistance to this mode of action in 165 different weed species worldwide to date. Whilst florasulam only has activity against broad-leaved weed species, a number of other herbicides in this mode of action group have activity against annual grass weed species and many of the reported cases of resistance occur in grass weeds.

To date, cases of resistance of annual broad-leaved weed species to HRAC group B (ALS inhibitors) mode of action in Europe are less widespread and occur in a lower number of species, compared to the rest of the world. Currently, resistance to ALS inhibitors has been recorded in 23 different annual broad-leaved weed species in Europe, of which only in 9 species in countries within Central registration zone, as recorded on www.weedscience.org.

Cross resistance in a weed occurs when exposure to one herbicide confers resistance to other herbicides in the same mode of action group. Without evidence otherwise, it is usual to consider that biotypes with developed resistance to one herbicide are also resistant to other herbicides with the same mode of action. Therefore, combinations of various herbicides from same chemical class cannot be used as a resistance management tool.

Multiple resistance occurs when weed biotypes with resistance to one mode of action are also resistant, or show reduced sensitivity, to one or more other herbicidal modes of action.

Cases of multiple resistance in Europe to HRAC mode of action B herbicides, to which florasulam belongs, include biotypes of *Kochia scoparia* first reported in 1996 in Czech Republic that are also resistant to HRAC mode of action group C2 herbicides (Ureas and amides), biotypes of *Papaver rhoeas* reported in Spain (in 1993), France (in 2016), Greece (in 2002) and Italy (in 1998), and *Sinapis arvensis* reported in Turkey (in 2008) that are also resistant to other HRAC group O (synthetic auxins) herbicides and biotypes of *Conyza sumatrensis* reported in France (in 2016) that are also resistant to other HRAC group G (EPSP synthase inhibitors) herbicides.

The resistance risk analysis should be carried out following EPPO Guideline PP 1/213(2). The actual risk for the evolution of resistance depends on three different parameters: mechanism of resistance against the compound, biology of the weed species and agronomic factors

Most annual broad-leaved weed species generally produce only one generation per year and the development of resistance is normally a relatively slow process. It is difficult to establish the likelihood of individual weed species developing resistance to an herbicide.

Numbers of recorded cases of resistance to HRAC mode of action B herbicides and numbers of broad-leaved weed species with developed resistance to are relatively high. The active ingredient florasulam has a very short half-life in soil. Therefore, with less persistence in the soil, selection pressure towards less sensitive biotypes is short, which significantly lowers the risk for development of resistant weed populations.

The risk of resistance arising from the use of florasulam is therefore considered to be medium.

Control of annual broad-leaved weed species in cereal crops in commercial practice typically involves more than one application of a herbicide and tank mixtures of herbicides, utilising multiple active substances with different modes of action, particularly in winter cereal crops, which reduces the potential for the development of resistance.

Crop rotation of cereal crops particularly with spring sown broad-leaved crops, with the use of different herbicide modes of action in these crops and for control of weeds between crops, also reduces the potential for the development and spread of resistant weed biotypes.

The risk management strategy to reduce the risk of resistance developing to florasulam from the use of FLD-HER 306 SE is based on Good Agricultural Practices (GAP) and current measures advocated by HRAC including correctly identifying the problem for which a herbicide is required, application at the label recommended rate at the correct time of year and to the weed at the correct stage of growth, utilisation of chemistry with different herbicidal modes of action and non-chemical methods of control (including soil management and crop rotation) dependent upon the situation and to routinely check the performance of the crop protection product to ensure adequate efficacy is achieved.

Further to these measures, the risk management strategy to reduce the risk of resistance developing directly from the use of FLD-HER 306 SE is specifically based on:

- Maximum of one application per crop
- Maintaining the recommended label rate as that shown to give effective control
- Application to be made when weeds are at the most susceptible stages of development
- Use in sequences with herbicides with different modes of action
- Use of herbicides with different modes of action in subsequent seasons
- Good agronomical practices: crop rotations, soil management work...

This should ensure there is no adverse shift in the sensitivity of weed populations to the product.

2,4 – D

Auxinic herbicides such as 2,4-D – one of the first widely used herbicides – have been used as effective weed control agents since the introduction of 2,4-D herbicides in 1945 (Smith, 1989). Despite its decades-long worldwide use, resistance against 2,4-D has been found in only 28 different weed species, although the first cases had already been reported in wild carrot (*Daucus carota*) and spreading dayflower (*Comelina diffusa*) in 1957 (Switzer, 1957; Hilton, 1957; Heap, 2016).

The herbicidal mechanism of action of 2,4-D is considered to be activation of the auxin receptor system (TIR1 and related receptor proteins), which results in permanent up-regulation of auxin responses in plants. These include changes in the actin cytoskeleton, followed by up-regulation of the plant hormones ABA and ethylene, and high production levels of reactive oxygen species (ROS). In the end, 2,4-D treatment results in cell wall reorganization, membrane leakage and cell death.

In most cases of resistance to 2,4-D and auxinic herbicides, details of the mechanisms of resistance are not known. Increased absorption of 2,4-D (Kohler et al., 2004), reduced translocation (Weinberg et al., 2006), increased metabolism of 2,4-D (Hagin et al., 1970) and differential binding to auxin-binding proteins (Webb and Hall, 1995) have all been implicated with herbicide resistance. However, reading the published 2,4-D resistance literature with an eye on possible auxin transport impairment shows that similar mechanisms to that described by Goggin et al. (2016) might also be the cause of 2,4-D resistance in other cases (Riar et al., 2011; Rey-Caballero et al., 2016).

The claim that 2,4-D resistance is unlikely to evolve because of the complex and essential functions that auxin plays in plants is unsubstantiated. In many cases where resistance has evolved to synthetic auxins, the biochemical mechanism is unknown. However, in at least two cases (*Kochia scoparia* and *Sinapis arvensis*), resistance is conferred by a single dominant allele, indicating that resistance could develop and spread quite rapidly.

The global spread of herbicide-resistant weeds is a serious problem requiring a serious rethinking of our approach to weed management.

In our opinion resistance risk against glyphosate and 2,4-D in Poland may be defined as medium.

The resistance risk from unrestricted use is unacceptable. However, **the use of single applications of label rates of Konik 306 SE (product code: FLD-HER 306 SE) at the right timing in accordance with the label recommendations is considered to present a low risk of resistance development when used within good agricultural practice (crop rotation, alternative modes of action, cultivation).**

It is necessary to: apply integrated weed management practices. Where possible use multiple herbicide modes of action with overlapping weed spectrums in rotation, sequences or mixtures. Visit fields after herbicide application to ensure control has been achieved. Avoid allowing weeds to reproduce by seed or propagating vegetatively.

Due to the different mode of action of both active substances florasulam and 2,4-D, the occurrence of resistance to this herbicide is minimal. It is worth noting that the application of the formulated mixture of florasulam and 2,4-D has been widely adopted for weed control in winter cereals to manage ALS - resistant crops.

3.3.2 Adverse effects on treated crops

The applicant carried out 33 selectivity trials of spring wheat, spring barley, oat, winter wheat, winter triticale, winter barley, rye and maize on a wide range of commercially grown varieties. All the trials have been presented in Part B - Section 3. Application of FLD-HER 306 SE in a dose of 0.6 L/ha caused no adverse effects on yield quantity and quality (grain yield, weight of hectoliter of the grain, the weight of thousand grain, moisture content of cereals as well as cobs number and cobs weight of maize) in selectivity trials.

Moreover no phytotoxic effect (changes in growth, plant height, tillering, dates of succeeding growth stages, thinning out of plants, discolorations, necroses, deformations, yield quantity and quality) of FLD-HER 306 SE was recorded in efficacy trials.

3.3.3 Observations on other undesirable or unintended side-effects

No undesirable or unintended side-effects, impact on succeeding crops, impact on other plants including adjacent crops, effects on beneficial and other non-target organisms were observed in conducted field trials.

Side effects on adjacent crops

According to *2,4-D Renewal Assessment Report. Volume 1. February 2013 (2,4-D RAR.2013)* “spray drift must be avoided to susceptible plants such as oil seed rape, sunflower, cotton, tobacco, vines, fruit trees, ornamentals and vegetables”.

No side effects on adjacent crops were reported in *Renewal Assessment Report of Florasulam (Florasulam RAR.2013)*.

Impact on other plants including adjacent crops

None of the efficacy/crop safety trials reported any effects on adjacent crops or plants. Application of FLD-HER 306 SE according to the requirements of “Good Agricultural Practice” excludes lapses, e.g. overspray of boundary stripes, overdose or applications in other than the registered crops or at other application times. Furthermore, GAP avoids spray drift to adjacent crops by taking into account the wind speed, the droplet size and positioning of the spray boom. As FLD-HER 306 SE is intended for control of dicotyledonous weeds, the product may cause damages on dicotyledonous adjacent crops if it is misused.

Therefore, it is not expected that appropriate applications of FLD-HER 306 SE will lead to adverse effects on adjacent crops.

Impact on rotational crops

As it is stated in *2,4-D RAR. 2013*: “All crops under consideration (cereals and maize) may be grown in rotation but, according to the soil degradation studies evaluated in the framework of (...) Annex I renewal submission, the DT₉₀ value calculated for 2,4-D, was 24.8 days which is below the trigger value of 100 days. Relevant soil metabolites were also not identified. According to the European guidelines on rotational crops (EU 7524/VI/95 rev. 2, 1997) further investigation of residues in rotational crops is not required and relevant in these crops are not expected.” There are no objections to the selection of succeeding crops on fields exposed to 2,4-D, because during many years of its use, a high rate of its decomposition was demonstrated. For this reason, it is possible to re-sow cultivated plants even 4 weeks after the treatment.

Detailed studies with florasulam have shown a very low potential risk to succeeding plants (cabbage, carrot, sunflower and wheat). Based on the rate of dissipation of florasulam. Residues in soil and results from confined rotational crop residue studies, it was concluded that residues in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

Impact on succeeding crops

No specific plant-back restrictions related to FLD-HER 306 SE are required. However, in case of the need to sift the treated plantation (as a result of crop damage by frost, disease or pest), only maize and spring cereals can be grown on the same field after seedbed preparation (at the depth of min. 5 cm).

Summary of feeding studies in poultry, ruminants, pigs and fish

As it is stated in *2,4-D RAR. 2013*: “2,4-D is proposed for use on crops that might be fed to livestock (cereals and maize). Therefore the median and maximum dietary burdens for dairy ruminants, meat ruminants, poultry and pigs were below the trigger value of 0.1 mg/kg. Consequently no metabolism studies in livestock are required for ruminants, poultry or pigs and no new MRLs are to be proposed in the framework of this application since a significant intake was not identified for these types of livestock.”

No feeding studies in livestock were submitted and none have been conducted during assessment of *Florasulam RAR*. Considering the low levels of residues expected in livestock feed commodities from cereals and maize along with extrapolation of residue results from livestock nature of residue studies in goats and

hens, residues of florasulam in edible tissues, milk or eggs are not expected to be quantifiable (i.e. <0.01 mg/kg). Therefore, no livestock feeding studies are required.

Summary of effects of processing

According to *2,4-D RAR. 2013*: “As quantifiable residues of 2,4-D are not significant (<0.1 mg/kg), there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.”

As it is stated in *Florasulam RAR.2013*: “Quantifiable residues of florasulam were not found in cereal grains or maize grain, therefore it is not required to investigate the effect of industrial processing or household preparation.”

Effects on beneficial and other non-target organisms

In efficacy and phytotoxicity trials no adverse effect of FLD-HER 306 SE on beneficial organisms was observed. Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

Products contained 2,4-D and florasulam has been used for many years, not only Poland but also in other European countries. According to current knowledge of FLD-HER 306 SE does not pose any unacceptable risk to other plants also there was no adverse impact on beneficial organisms.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for determination of 2,4-D and florasulam in FLD-HER 306 SE was not evaluated as part of the EU review of 2,4-D and florasulam. Therefore, all relevant data are provided and are considered adequate.

The method for determination of florasulam and 2,4-D in FLD-HER 306 SE is based on high performance liquid chromatography technique (HPLC) with DAD detection wavelength 270 nm and external standard. In order to confirm method specificity, chromatograms of acetonitrile, placebo, standard and analysed sample were superimposed and compared.

There were no peaks interfering with the florasulam peak. The correlation coefficient was $R^2=0.9999$ (the criterion of acceptability is $R^2<0.99$). The relative standard deviation of instrument precision for the determined active substance was 0.33% (criterion of acceptability is $RSD \leq 1\%$). Acceptable relative standard deviation of repeatability for the determined active substance is $\leq 2.90\%$. The obtained results of 0.97% is acceptable. The accuracy of active ingredient determination was estimated by the recovery measurement. The average recovery value for the main component should be $100\pm 10\%$. The obtained result 101.8% is acceptable.

There were small peaks (< 3% of the total peak measured) interfering with the 2,4-D peak. The correlation coefficient was $R^2=0.9996$ (the criterion of acceptability is $R^2<0.99$). The relative standard deviation of instrument precision for the determined active substance was 0.34% (criterion of acceptability is $RSD \leq 1\%$). Acceptable relative standard deviation of repeatability for the determined active substance is $\leq 1.62\%$. The obtained results of 0.55% is acceptable. The accuracy of active ingredient determination was estimated by the recovery measurement. The average recovery value for the main component should be $100\pm 3\%$. The obtained result 100.5% is acceptable.

The method for determination of florasulam and 2,4-D in FLD-HER 306 SE fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure appropriate active substance determination in the formulation.

3.4.2 Analytical methods for residues

All analytical methods are active substances data and were evaluated during the EU review of 2,4-D and Florasulam. They were considered adequate. No additional studies have been performed.

2,4-D

EFSA Journal 2014;12(9):3812:

LC-MS/MS methods are available for the analysis of materials of plant and animal origin. However, the validation of these methods with regard to extraction efficiency and validation of the hydrolysis step are lacking, therefore a data gap has been identified. LC-MS/MS and GC-MS methods are available for soil and water, and an LC-MS/MS method is available for air. An LC-MS/MS method is available for blood and urine.

Noticed data gaps should be addressed at renewal of the Flod 306 SE.

Florasulam

EFSA Journal 2015; 13(1):3984

Residues of florasulam in food and feed of plant origin can be monitored with LC-MS/MS method with LOQs of 0.01 mg/kg in all commodity groups. Florasulam can be monitored in food of animal origin with LC-MS/MS with LOQs of 0.01 mg/kg in meat, liver, fat, milk and eggs. Residues of flo-rasulam in soil can be monitored by LC-MS/MS with a LOQ of 0.05 µg/kg. Appropriate LC-MS/MS method with a LOQ of 0.05 µg/L exists for monitoring florasulam in surface water and drinking water. Residues of florasulam in air can be monitored by LC-MS/MS with a LOQ of 1.3 mg/m3. LC-MS/MS method with LOQs of 0.05 mg/L exists for the determination of florasulam in body fluids. State whether submitted data are sufficient for evaluation. Data gaps and conditions for authorization should be listed, if appropriate.

Commodity/crop	Supported/ Not supported
Spring wheat	Supported
Spring triticale	Supported
Spring barley	Supported
Oat	Supported
Winter wheat	Supported
Winter triticale	Supported
Winter barley	Supported
Rye	Supported
Maize	Supported

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

No acute toxicity studies were performed for FLD-GEN 306 SE. The classification of FLD-HER 306 SE was based on the composition of the product and was performed by additivity formula according to the

Regulation (EC) of the European Parliament and of the Council No. 1272/2008 of December 16th, 2008 on classification, labelling and packaging of substances and mixtures. Details on composition and classification of formulants are provided in dRR Part C. It was assessed that FLD-HER 306 SE should be classified as:

- Acute Tox. 4, H302 - Harmful if swallowed.
- Acute Tox. 4, H332 - Harmful if inhaled.
- Eye Dam. 1, H318 - Causes serious eye damage.
- Skin Sens. 1, H317 - May cause an allergic skin reaction.

3.5.2 Operator exposure

Operator exposure to FLD-HER 306 SE was not evaluated as part of the EU review of 2,4-D and florasulam. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The operator exposure was assessed against the AOEL agreed in the EU review of 2,4-D and florasulam. No studies were available to determine the dermal absorption, default values as defined in the EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873) were used for the calculations.

Operator exposure was modelled using the EFSA model AOEM (Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015).

According to the model calculations, it can be concluded that the risk for the operator using FLD-HER 306 SE according to GAP is acceptable when operator is using workwear (arms, body and legs covered) and protective gloves during mixing/loading and during application.

3.5.3 Worker exposure

Worker exposure to FLD-HER 306 SE was not evaluated as part of the EU review of 2,4-D and florasulam. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Worker exposure was modelled using the EFSA model AOEM (Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015) and EUROPOEM II re-entry model (Hemmen et al (2002) Post-application exposure of workers to pesticides in agriculture, Report of the re-entry working group. EUROPOEM II project. FAIR3 CT96-1406).

The results of the exposure estimation shows that the use of FLD-HER 306 SE according to GAP, causes no health risk for the worker assuming the workwear (arms, body and legs covered) is used because the calculated exposure level to 2,4-D and florasulam is lower than the value of AOEL for this active substances when work wear is used.

However, it is forbidden to re-enter area treated with FLD-HER 306 SE containing 2,4-D (300 g/L) and florasulam (6.25 g/L) until spray deposit on plant surfaces has dried. Taking into account hygienic rules, it is recommended that a worker inspecting treated area was dressed properly (long trousers, long-sleeve shirt) and equipped with protective gloves. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.5.4 Bystander and resident exposure

Bystander and resident exposure to FLD-HER 306 SE was not evaluated as part of the EU review of 2,4-D and florasulam. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Bystander and resident exposure was modelled using the EFSA model AOEM (Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015), German bystander and resident model and EUROPOEM II MODEL bystander exposure.

The reference value acutely toxic active substance (RVAAS) for 2,4-D and florasulam is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards this active substance. The longer-term exposure of residents (children) to 2,4-D via re-entry and for the sum of all pathways using the EFSA calculator was estimated to be slightly above the systemic AOEL for 2,4-D. However, calculation performed with two other models (German bystander and resident model and EUROPOEM II MODEL bystander exposure) shows no exceedance of appropriate AOELs for 2,4-D and florasulam. It can be concluded that the incidental short-time exposure of bystander and resident (children and adult) to 2,4-D and florasulam contained in the formulation FLD-HER 306 SE causes no risk to human health if the product FLD-HER 306 SE is used according to GAP and buffer zone should be 5 m.

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

2,4-D

Stability of Residues

2,4-D residues were shown to be stable at least 18 months in high water-, high starch and dry matrices, when stored at -18 °C, and at least 12 months in high oil matrices when stored at -23 °C to -27 °C. 2,4-D residues were found to be chemically stable in beef matrices when stored frozen for 4 months (EFSA Journal 2014;12(9):3812). Sufficient stability has been demonstrated to support the residue data presented in this document.

No further data are required to support the proposed uses.

Metabolism in plants

No new data submitted in the framework of this application.

Plant and animal residue definition for monitoring and risk assessment: Sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D (Reg. (EU) 2019/1791, EFSA Journal 2014;12(9):3812)

No further data are required to support the proposed uses.

Magnitude of residues in plants

Spring wheat, Spring triticale, Spring barley, Oat

Proposed GAP:

BBCH 12-32, 1 application, 120-180 g as./ha, PHI: N/A

Winter wheat, Winter triticale, Winter barley, Rye

Proposed GAP:

BBCH 21-32, 1 application, 120-180 g as./ha, PHI: N/A

EU GAPs

Winter cereals, Spring cereals (EFSA Journal 2014;12(9):3812; SANCO/11961/2014 – rev. 5, 6/10/2017)

BBCH 21-32 (winter cereals), 11-32 (spring cereals); 1 application 750 g as./ha; PHI: N/A

Proposed GAPs for cereals are less critical than EU GAPs (in relation to application rates).

Sufficient trials on cereals (wheat, barley and oats) are available to support the proposed uses.

All studies were performed with higher application rates compared to the intended rate. They were considered in the risk assessment since all residue values were below the LOQ. Residues of 2,4-D are comparable in trials conducted with different formulations and in different European regions.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (Reg. (EU) 2019/1791: barley, oat - 0.05 mg/kg; wheat including triticale and rye -2.0 mg/kg).

According to the SANTE/2019/12752 extrapolation from the residue trials on barley may be extrapolate to oat, rye and wheat and residue trials on wheat may be extrapolate to oat, rye and barley, before forming of the edible part. Application to cereals is intended at early growth stages (up to BBCH 32), therefore extrapolation is possible.

Maize

Proposed GAP:

BBCH 12-16, 1 application, 120-180 g as./ha, PHI: N/A

GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 11-16, PHI n.a., outdoor

Proposed GAP for maize is less critical than EU GAPs (in relation to application rates).

Sufficient trials on maize are available to support the proposed uses.

All studies were performed with higher application rates compared to the intended rate. They were considered in the risk assessment since all residue values were below the LOQ. Residues of 2,4-D are comparable in trials conducted with different formulations and in different European regions.

The residues arising from the proposed uses will not exceed the MRLs established for maize (Reg. (EU) 2019/1791; 0.05 mg/kg).

Magnitude of residues in livestock

The new animal model calculation (Excel spreadsheet Animal model 2017) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded. Supplementary livestock feeding studies are not required. Calculations provided by the applicant are accepted.

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

As quantifiable residues of 2,4-D are not expected in edible part of crops based on available residue data, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed.

Florasulam

Stability of Residues

Florasulam residues stable in wheat matrices (whole plant, straw and grain) for a period of at least 18.7 months (EFSA Journal 2015; 13(1):3984)

Sufficient stability has been demonstrated to support the residue data presented in this document.

No further data are required to support the proposed uses.

Metabolism in plants and animals

The data evaluated during the Annex I inclusion and renewal process of the active substance are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Plant and animal residue definitions for monitoring: Florasulam (Reg. (EU) No 1317/2013)

Plant residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam and provisionally 4-OH- phenyl-florasulam (data gap)

Animal residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam pending assessment with regard to 4-OH-phenyl-florasulam

Conversion factor (monitoring to risk assessment): For milk, liver, kidney and eggs: 1

The data gap concerns the further toxicological evaluation of the plant metabolite 4-OH- phenyl-florasulam.

Magnitude of residues in plants

Spring wheat, Spring triticale, Spring barley, Oat

Proposed GAP:

BBCH 12-32, 1 application, 2.5-3.75 g as./ha, PHI: N/A

Winter wheat, Winter triticale, Winter barley, Rye

Proposed GAP:

BBCH 21-32, 1 application, 2.5-3.75 g as./ha, PHI: N/A

The proposed use of florasulam on wheat and barley is less critical than the critical GAP evaluated in the framework of the renewal of the substance.

EU GAP (RAR): 1 x 6.25 g as/ha, BBCH 45, PHI N/A

EU GAP (review of the MRLs according to article 12): 1x 7.5 g as/ha, up to BBCH 49, PHI N/A

Due to the early growth stage of application, data were pooled from residue trials on wheat and barley.

Sufficient trials on cereals are available to support the proposed uses.

Residues from trials are all below 0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (0.01 mg/kg; Regulation (EU) No 1317/2013 of 16 December 2013)

According to the SANTE/2019/12752 extrapolation from the residue trials on barley may be extrapolate to oat, rye and wheat and residue trials on wheat may be extrapolate to oat, rye and barley, before forming of the edible part. Application to cereals is intended at early growth stages (up to BBCH 32), therefore extrapolation is possible.

Maize

Proposed GAP:

BBCH 12-16, 1 application, 2.5-3.75 g as./ha, PHI: N/A

EU GAP (RAR):

BBCH 11-20, 1 application 5.0 g as./ha, PHI: N/A

The proposed use of florasulam on maize is less critical than the critical GAP evaluated in the framework of the renewal of the substance.

Sufficient trials on cereals are available to support the proposed uses.

Residues in grain from trials are all below 0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for maize (0.01 mg/kg)

Magnitude of residues in livestock

The new animal model calculation (Excel spreadsheet Animal model 2017) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded. Supplementary livestock feeding studies are not required. Calculations provided by the applicant are accepted.

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

As quantifiable residues of florasulam are not expected in edible part of crops based on available residue data, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed.

EFSA Journal 2015; 13(1):3984: *In the section on residues data gaps were identified with regard to residues in animal commodities and rotational crops. Nonetheless, the margin of safety in the consumer risk assessment is considered big even if the potentially relevant toxicological burden for consumers via their diet might have been underestimated in the current assessment.*

Residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

Proposed uses are accepted

3.6.1 Consumer exposure

The chronic and acute consumer exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population.

Consumer risk assessment for 2,4-D

ADI	0.02 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	114 % (based on DK child Diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	46 % (based on NL toddler Diet)
ARfD	0.3 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	<u>Unprocessed commodities: % ARfD</u> 9,63% Wheat 0,11% Maize/corn 0,09% Barley

	<u>Processed commodities: %ARfD</u> 8,1% Wheat / milling (flour) 3,7% Wheat / milling (wholemeal)-baking 0,4% Maize / oil 0,1% Barley / cooked 0,0% Maize / processed (not specified) 0,0% Barley / milling (flour)
NTMDI (% ADI) **	Not relevant.
NEDI (% ADI)**	Not relevant.
NESTI (% ARfD) **	Not relevant.

* include raw and processed commodities if both values are required for PRIMo rev. 3.1

** if national model is available

The proposed uses of 2,4-D in the formulation FLD-HER 306 SE does not represent unacceptable chronic and acute risks for the consumer.

Consumer risk assessment for florasulam

ADI	0.05 mg/kg bw/day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	2 % (based on NL toddler Diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not relevant. TMDI < 100%.
ARfD	ARfD was not deemed necessary.
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Not relevant. ARfD was not deemed necessary.
NTMDI (% ADI) **	Not relevant
NEDI (% ADI)**	Not relevant
NESTI (% ARfD) **	Not relevant

* include raw and processed commodities if both values are required for PRIMo rev. 3.1

** if national model is available

The proposed uses of florasulam in the formulation FLD-HER 306 SE do not represent unacceptable acute and chronic risks for the consumer.

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

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

PECs modeling was performed with ESCAPE v. 2 and simple equations included in FOCUS soil persistence document issued in 1997. Since algorithm of modeling in both tools differ, slightly different results were obtained. PECs for formulation was obtained from PECs for 2,4-D taking into account content of active substance and density of the formulation FLD-HER 306 EC. For further risk assessment worst case PECs values were used.

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

PEC_{gw} for active substances and their metabolites after application to cereals and maize were calculated with PELMO 5.5.3 and PEARL 4.4.4 for FOCUS groundwater scenarios that may be relevant for central

Europe i.e. Châteaudun, Hamburg, Jokioinen, Kremsmünster and Okehampton. Other scenarios were not taken into account since are not relevant.

The PEC_{gw} for 2,4-D and its metabolites 2,4-DCP, 2,4-DCA and 4-CP were below the trigger value of 0.1 $\mu\text{g/L}$ for all scenarios. The PEC_{gw} for florasulam and its metabolites 5-OH-florasulam and DFP-ASTCA were below the trigger value of 0.1 $\mu\text{g/L}$ for all scenarios. PEC_{gw} for the metabolites ASTCA and TSA were above 0.1 $\mu\text{g/L}$ but these metabolites are of no toxicological concern so it may be therefore concluded that the threshold of concern 0.75 $\mu\text{g/L}$ is not exceeded. Scenarios relevant for Poland are Châteaudun, Hamburg and Kremsmünster.

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

PEC_{sw} for active substances and their metabolites after application to cereals and maize were calculated with FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v.5.0.1 for surface water scenarios that may be relevant for central Europe i.e. D1, D2, D3, D4, R1. Other scenarios were not taken into account since are not relevant. Scenarios relevant for Poland are D3, D4, R1. PEC_{sw} values were used in aquatic risk assessment.

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

The fate and behaviour of 2,4-D and florasulam in air was evaluated during the EU review. No additional studies have been performed.

The vapour pressure at 20 °C of the 2,4-D is $< 10^{-5}$ Pa. Hence the 2,4-D is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the 2,4-D due to volatilization with subsequent deposition is not expected to occur. Additionally, DT50 value in the atmosphere is below 2 days indicating that it would not be persistent in air.

The vapour pressure at 25 °C of the florasulam is $< 10^{-5}$ Pa. Hence the florasulam is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the florasulam due to volatilization with subsequent deposition is not expected to occur. Additionally, DT50 value in the atmosphere is below 2 days indicating that it would not be persistent in air.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

Effects on birds for FLD-HER 306 SE were not evaluated as part of the EU review of 2,4-D and florasulam. However further data on FLD-HER 306 SE is not relevant as data for each active substance on toxicity to birds are considered essential. It is possible to extrapolate from data for each active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for FLD-HER 306 SE with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on birds was carried out according to the latest guidance for risk assess-

ment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of FLD-HER 306 SE to birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substances, as well as SV90 and SVM.

Drinking water exposure (leaf scenario) has not been estimated since it is not relevant. Drinking water exposure (puddle scenario) has not been performed since the ratio of effective application rate to relevant endpoint does not exceed 50 (Koc < 500 L/kg).

Exposure for earthworm-eating birds and fish-eating birds via secondary poisoning was assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substances as well as exposure estimated from predicted environmental concentration of 2,4-D and florasulam in earthworms and fishes.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to birds from the proposed use of FLD-HER 306 SE. No risk mitigations are required.

Terrestrial vertebrates (other than birds)

Effects on mammals for FLD-HER 306 SE were not evaluated as part of the EU review of 2,4-D and florasulam. However further data on FLD-HER 306 SE is not relevant as data for each active substance on toxicity to mammals are considered essential. It is possible to extrapolate from data for each active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for FLD-HER 306 SE with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on terrestrial vertebrates other than birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of FLD-HER 306 SE to terrestrial vertebrates other than birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with 2,4-D and florasulam, as well as SV90 and SVM. Since preliminary reproductive risk assessment failed further calculations were performed taking into account detailed information on crop, rate and BBCH scale during application. The selected focal species used in refined risk assessment was bank vole.

Drinking water exposure (puddle scenario) has not been performed since the ratio of effective application rate to relevant endpoint does not exceed 50 (Koc < 500 L/kg).

Exposure for earthworm-eating mammals and fish-eating mammals via secondary poisoning was assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with 2,4-D and florasulam as well as exposure estimated from predicted environmental concentration of 2,4-D and florasulam in earthworms and fishes.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to mammals from the proposed use. No risk mitigations are required.

3.8.2 Effects on aquatic species

Effects on aquatic organisms for FLD-HER 306 SE were not evaluated as part of the EU review of 2,4-D and florasulam. Acute toxicity studies of FLD-HER 306 SE to invertebrates, algae and aquatic plants were submitted in this dossier.

Risk assessments for FLD-HER 306 SE with the proposed use pattern was carried out according to the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

PEC/RAC values were calculated on the basis of PEC calculations as well as worst case toxicity endpoints from studies for active substance, metabolites and formulation. PEC/RAC values were less than 1 so it can be concluded that the application of FLD-HER 306 SE does not pose unacceptable risk for aquatic organisms under condition that appropriate risk mitigations are applied.

For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that FLD-HER 306 SE used at max. rate of 0.6 L/ha to protect cereals and maize according to proposed GAP does not pose unacceptable risk to aquatic organisms under condition that: 5m buffer zone is applied in case of spring and winter cereals and 5m vegetated buffer zone in case of maize

The proposed classification of the product FLD-HER 306 SE is:

Aquatic Acute 1, H400

Aquatic Chronic 1, H410

3.8.3 Effects on bees

Effects on bees for FLD-HER 306 SE were not evaluated as part of the EU review of 2,4-D and florasulam. Toxicity studies of FLD-HER 306 SE to bees were submitted in this dossier.

The evaluation of the acute risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). Since for chronic exposure no adopted guidelines are available, chronic risk assessment was performed according to Draft EFSA Guidance (EFSA Journal 2013;11(7):3295) - although this has not been adopted.

The acute risk of FLD-HER 306 EC to honeybees was assessed from HQ between toxicity endpoints, estimated from acute oral and contact studies with active ingredients and formulated product as well as the maximum single application rate. The HQ values were considerably less than 5 that means product FLD-HER 306 SE does not pose unacceptable acute oral and contact risk to honeybees.

The chronic risk of FLD-HER 306 EC to honeybees was assessed from ETR between exposure and chronic toxicity endpoint, estimated from 10d chronic study with formulated product FLD-HER 306 SE. The ETR values were considerably less than 0.03. Results indicate that the product does not pose unacceptable chronic risk to bees.

The chronic risk of FLD-HER 306 EC to bee larvae was assessed from ETR between exposure and chronic toxicity endpoint, estimated from bee larvae chronic toxicity study with formulated product FLD-HER 306 SE. The ETR values were considerably less than 0.2. Results indicate that the product does not pose

unacceptable chronic risk to bee larvae.

It can be concluded that FLD-HER 306 SE used at max. application rate of 0.6 L/ha to protect cereals and maize according to proposed GAP, does not pose unacceptable risk to bees and bee larvae. No risk mitigations are required.

3.8.4 Effects on other arthropod species other than bees

Effects on non-target arthropods for FLD-HER 306 SE were not evaluated as part of the EU review of 2,4-D and florasulam. Toxicity studies of FLD-HER 306 SE to non-target arthropods were sub-mitted in this dossier.

Risk assessments for FLD-HER 306 SE with the proposed use pattern was carried out according to the guidance for risk assessment for arthropods “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and in consideration of the recommendations of the guidance document ESCORT 2.

The risk of FLD-HER 306 EC to non-target arthropods was assessed from in-field and off-field HQ between toxicity endpoints, estimated from extended laboratory studies with active ingredients and formulated product as well as the maximum single application rate. The HQ values were considerably less than 2, indicating that the product poses a low risk to non-target arthropods. It can be concluded that FLD-HER 306 SE used at max. application rate of 0.6 L/ha to protect cereals and maize according to proposed GAP, does not pose unacceptable in-field and off-field risk to non-target arthropods. No risk mitigations are required.

3.8.5 Effects on soil organisms

Effects on earthworms and soil micro-organisms for FLD-HER 306 SE were not evaluated as part of the EU review of 2,4-D and florasulam. The earthworm chronic toxicity study and nitrogen transformation test for FLD-HER 306 SE were submitted in this dossier.

Risk assessments for FLD-HER 306 SE with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

Earthworms, collembola and *Hypoaspis*

The acute and chronic risk of FLD-HER 306 SE to earthworms, collembola and *Hypoaspis* was assessed from toxicity exposure ratios (TER) between the selected toxicity endpoint for the active ingredient, metabolites and the formulated product FLD-HER 306 SE as well as appropriate predicted environmental concentrations in soil (PECs). The acute and chronic TER values were greater than the trigger of 10 and 5 respectively, indicating an acceptable risk to earthworms, collembola and *Hypoaspis* following application of FLD-HER 306 SE at maximum rate of 0.6 L/ha. No risk management measures are required.

Micro-organisms

The risk of FLD-HER 306 SE to soil micro-organisms was evaluated by comparison of no-effect concentration in soil (PECs), derived from laboratory tests for active substances, metabolites and the formulated product FLD-HER 306 SE with predicted application concentrations (PECs) obtained for active substanc-

es, metabolites and the formulation. According to the performed risk assessment it was assessed that the application of FLD-HER 306 SE at maximum rate of 0.6 L/ha does not pose unacceptable risk to soil micro-organisms. No risk mitigations are required.

3.8.6 Effects on non-target terrestrial plants

Effects on non-target terrestrial plants for FLD-HER 306 SE were not evaluated as part of the EU review of 2,4-D and florasulam. The studies on seedling emergence and vegetative vigour for FLD-HER 306 SE were submitted and evaluated in this dossier.

Risk assessments for FLD-HER 306 SE with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

The risk of FLD-HER 306 SE to non-target plants was assessed from toxicity exposure ratios between toxicity endpoints for the formulation FLD-HER 306 SE and off-field predicted environmental rate. The TER values were greater than the trigger of 5, indicating an acceptable risk to non-target terrestrial plants following application of FLD-HER 306 SE on cereals and maize at the max. application rate of 0.6 L/ha. No risk mitigations are required.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites of ASTCA and TSA are predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required. Based on this assessment it could be concluded that none of the metabolites should be considered as relevant.

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

FLD-HER 306 SE contains two active substances 2,4-D and florasulam. Neither io2,4-D nor florasulam are candidates for substitution. A comparative assessment was therefore not considered necessary.

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

TOX:

klasyfikacja z frazą H318 obliguje do zwrotu: Niebezpieczeństwo

Na etykiecie należy umieścić dodatkowe środki ograniczające ryzyko:

- „Po zastosowaniu preparatu w widocznych miejscach na polu umieścić tablice ostrzegawcze: „Zakaz wstępu osób niepowołanych do obszaru poddanego działaniu środków ochrony roślin”. Tablice powinny pozostać do czasu zbioru roślin.”
- „Podczas oprysku należy stosować strefę ochronną w odległości co najmniej 5 m od budynków mieszkalnych/siedlisk oraz osób postronnych”.

Posiadacz zezwolenia:

Pestila Spółka z ograniczoną odpowiedzialnością, Studzianki 24a, 97-320 Wolbórz,
tel./fax: +48 446164375, e-mail: info@pestila.pl.

KONIK 306 SE

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej: **florasulam** (substancja z grupy triazolopirymidyn)

- **6,25 g/l** (0,58 %)

2,4-D (substancja z grupy fenoksykwasów) - **300 g/l** (28,06 %)

Zezwolenie MRiRW nr R - /2021 z dnia .2021 r.



Uwaga Niebezpieczeństwo

- | | | |
|---------|---|---|
| H290 | – | Może powodować korozję metali. |
| H302 | – | Działa szkodliwie po połknięciu |
| H332 | – | Działa szkodliwie w następstwie wdychania. |
| H318 | – | Powoduje poważne uszkodzenie oczu. |
| H317 | – | Może powodować reakcję alergiczną skóry. |
| H410 | – | Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki. |
| EUH 208 | – | Zawiera 2,4-D 2EHE. Może powodować wystąpienie reakcji alergicznej. |
| EUH 401 | – | W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia. |
| P261 | – | Unikać wdychania rozpylonej cieczy. |

- P264 – Dokładnie umyć ręce po użyciu.
- P280 – Stosować rękawice ochronne/odzież ochronną/ochronę twarzy.
- P301+P312 – W PRZYPADKU POŁKNIECIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.
- P302 + P352 – W przypadku dostania się na skórę: umyć dużą ilością wody z mydłem.
- P304+P340 – W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
- P305+P351+P338 – W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć.
- P333+P313 – W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
- P391 – Zebrać wyciek.

OPIS DZIAŁANIA

Środek chwastobójczy w formie koncentratu stałych cząstek i małych kapsulek do rozcieńczania wodą, stosowany nalistnie, przeznaczony do wiosennego zwalczania jednorocznych i wieloletnich chwastów dwuliściennych w pszenicy ozimej, jęczmieniu ozimym, życie, pszenżycie ozimym, jęczmieniu jarym, pszenicy jarej, ~~owsie pszenżycie jarym, mieszanekach zbożowych~~ i w kukurydzy.

Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych.

DZIAŁANIE NA CHWASTY

Konik 306 SE jest herbicydem zawierającym dwie substancje czynne: florasulam oraz 2,4-D (tzn. w formie estru etyloheksylowego). Konik 306 SE jest herbicydem o działaniu układowym, pobierany jest przez liście chwastów, a następnie szybko przemieszczany w całej roślinie powodując jej deformację i zahamowanie wzrostu, co w efekcie powoduje zamieranie całego chwastu. Florasulam blokuje działanie enzymów podczas syntezy aminokwasów; 2,4-D hamuje działanie hormonów roślinnych odpowiedzialnych za wzrost roślin oraz zakłóca proces rozwoju komórek.

W warunkach optymalnych, to jest podczas ciepłej i wilgotnej pogody efekt działania środka Konik 306 SE jest szybszy, w warunkach niskich temperatur (około 5°C) całkowite zniszczenie chwastów następuje po około 3 tygodniach. Środek zwalcza chwasty, gdy minimalna temperatura dobową w ciągu 6 dni po wykonaniu zabiegu wynosi powyżej 5°C. Środek najskuteczniej niszczy chwasty znajdujące się w fazie 2-6 liści. Przytulię czepną zwalcza skutecznie do wysokości 20 cm, a chwasty rumianowate do wysokości 25 cm. Konik 306 SE skutecznie niszczy chwasty odporne na atrazynę np.: komosa biała, ~~psianka czarna~~, szarłat szorstki.

Chwasty wrażliwe na środek w dawce 0,4 l/ha: ~~jasnota różowa (LAMAM), jasnota purpurowa (LAMPU)~~, gwiazdnica pospolita (STEME), chaber bławatek (CENCY), tasznik pospolity (CAPBP), rumian polny (ANTAR), przytulia czepna (GALAP), maruna bezwonna (MATIN), tobołki polne (THLAR), mak polny (PAPRH), niezapominajka polna (MYOAR), komosa biała (CHEAL), szarłat szorstki (AMARE).

Chwasty wrażliwe na środek w dawce 0,6 l/ha: bodziszek drobny (GERPU), jasnota różowa (LAMAM), jasnota purpurowa (LAMPU), gwiazdnica pospolita (STEME), chaber bławatek (CENCY), tasznik pospolity (CAPBP), rumian polny (ANTAR), przytulia czepna (GALAP), ~~samosiowy rzepak (BRSNW)~~, maruna bezwonna (MATIN), tobołki polne (THLAR), mak polny (PAPRH), niezapominajka polna (MYOAR), komosa biała (CHEAL), szarłat szorstki (AMARE).

Chwasty średnio wrażliwe na środek w dawce 0,4 l/ha: jasnota różowa (LAMAM), jasnota purpurowa (LAMPU), dymnica pospolita (FUMOF), bodziszek drobny (GERPU), rdestówka powojowata (POLCO), ~~fiolka polna (VIOAR), przetacznik błuszczykowy (VERHE)~~, rdest ptasi (POLAV)

Chwasty średnio wrażliwe na środek w dawce 0,6 l/ha: dymnica pospolita (FUMOF), ~~bodziszek drobny (GERPU)~~, fiołek polny (VIOAR), przetacznik bluszczykowy (VERHE), przetacznik perski (VERPE), ~~bodziszek drobny (GERPU)~~, rdestówka powojowata (POLCO), rdest ptasi (POLAV)

Chwasty średnio odporne na środek w dawce 0,4 l/ha: fiołek polny (VIOAR), przetacznik bluszczykowy (VERHE), przetacznik perski (VERPE)

Chwasty średnio odporne na środek w dawce 0,6 l/ha: przetacznik trójlistkowy (VERTR)

Chwasty odporne na środek w dawce 0,4 l/ha: przetacznik trójlistkowy (VERTR)

STOSOWANIE ŚRODKA

Pszenica ozima, jęczmień ozimy, pszenżyto ozime, żyto, jęczmień jary, pszenica jara, ~~pszenżyto jare~~, owies, ~~mieszanki zbożowe~~.

Maksymalna dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,4-0,6 l/ha

Termin stosowania środka: stosować wiosną od fazy 2-3 liści do fazy drugiego kolanka (BBCH 12-32)

Zalecana ilość wody: **200-300 l/ha**

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Kukurydza

Maksymalna dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha

Termin stosowania środka: stosować w fazie 2-6 liści kukurydzy (BBCH 12-16)

Zalecana ilość wody: **200-400 l/ha**

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

UWAGI:

1. W przypadku silnego zachwaszczenia oraz chwastów znajdujących się w fazie powyżej 6 liści (okółków) stosować dawkę 0,6 l/ha.
2. W przypadku występowania chwastów średnio wrażliwych stosować dawkę 0,6 l/ha.
3. Środek powoduje zahamowanie rozwoju roślin fiołka polnego i jasnot w danej fazie. Zniszczenie ocenia się wówczas do 80 % skuteczności po zastosowaniu dawki 0,6 l/ha.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w glebie w ciągu okresu wegetacji nie stwarzając zagrożenia dla roślin uprawianych następczo.

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

Przestrzegać zaleceń dotyczących następstwa roślin obowiązujących dla herbicydów stosowanych w mieszaninach ze środkiem Konik 306 SE.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

1. W niesprzyjających warunkach pogodowych (np. susza), po kilku dniach od zastosowania, środek może spowodować na niektórych odmianach kukurydzy przemijające odbarwienia liści, które nie mają negatywnego wpływu na jakość i wielkość plonu.

2. Przed użyciem herbicydu Konik 306 SE w kukurydzy należy skontaktować się z hodowcą odmiany lub posiadaczem zezwolenia dla środka Konik 306 SE, aby upewnić się czy uprawiana odmiana kukurydzy nie reaguje ujemnie na te herbicydy.
3. W przypadku stosowania mieszanin zbiornikowych należy stosować się do zaleceń stosowania wszystkich środków mieszanych.
4. Środka nie stosować:
 - na rośliny mokre, chore i uszkodzone,
 - w zbożach z wsiewką roślin motylkowatych,
 - gdy minimalna temperatura w dniu zabiegu oraz przez 6 kolejnych dni wynosi 5°C,
 - w temperaturze powietrza poniżej 5°C i powyżej 25°C,
 - w czasie nadmiernej suszy,po nocnych przymrozkach oraz przed spodziewanymi przymrozkami.
5. Podczas stosowania środka nie dopuścić do:
 - znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym miesadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w miesadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.

W przypadku stosowania środka w mieszaninie z innymi środkami przestrzegać ściśle zaleceń dotyczących sporządzania cieczy użytkowej tych środków.

W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy należy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

Ze względu na bardzo dużą wrażliwość niektórych roślin uprawnych nawet na znikome ilości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w innych roślinach niż zalecane.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe 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.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

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

Środki ostrożności dla osób stosujących środek:

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

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

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.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 4-5 m od zbiorników i cieków wodnych w uprawie zbóż jarych i ozimych oraz 5-metrowej zadarnionej strefy w uprawie kukurydzy.

~~W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od terenów nieużytkowanych rolniczo.~~

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji): Dla ludzi - nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.
Dla zwierząt - na tereny potraktowane środkiem nie wpuszczać zwierząt gospodarskich, a zwłaszcza bydła mlecznego, przez 21 dni od zabiegu.

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

Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić rośliny uprawiane następnie: Należy uwzględnić następstwo roślin

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 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.

Okres ważności - ~~2 lata~~ 1 rok

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letters of Access

Letters of access are provided in a separate appendixes.

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
Section B1-B2 and B4: Identity, Physical and Chemical Properties, Further information							
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.6.2 KCP 2.8.6.3 KCP 2.8.7.2	Zajac S.	2019	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.2.1	Śliwa P.	2019	FLD-HER 306 SE Determination of explosive properties Report No BW-02/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 2.2.2 KCP 2.3.1 KCP 2.3.3	Flasińska P.	2019	FLD-HER 306 SE Determination of flash point, auto-ignition temperature and oxidizing properties. Report No BC-09/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.4.1 KCP 2.4.2 KCP 2.6.1 KCP 2.7.1	Zajac S.	2019	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Stage 3: Determination of physicochemical properties of preparation stored at temperature 54±2°C for 14 days. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.5.1	Arévalo E.	2019	FLD-HER 306 SE Determination of viscosity. Report No BF-17/19-02 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.5.2	Łysik A.	2019	FLD-HER 306 SE Determination of surface tension. Report No BF-17/19-03 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 2.7.1/01	Zajac S.	2019	FLD-HER 306 SE. Determination of active substances content of preparation in COEX bottle. Stage 1: Determination of active substances content of initial preparation. Stage 3: Determination of active substances content of preparation stored at temperature 54±2°C for 14 days. Report No 007/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.7.1/02	Gutowska I.	2019	FLD-HER 306 SE (2,4-D 300 g/L + florasulam 6.25 g/L) Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation. Report No BA-21/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.7.1/03	Gutowska I.	2020	Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation after the accelerated storage Report No BA-09/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished.	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.7.1/04	Grodowska K.	2020	Analysis of FLD-HER 306 SE before and after ageing tests to determine content of dioxins and furans. Report No K458/KG Selvita Services Sp. z o.o. GLP Yes Unpublished.	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 2.7.6	Zajac S.	2020	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Stage 4: Determination of physicochemical properties of preparation stored at temperature 20±2°C for 1 year. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.11	Arévalo E.	2019	FLD-HER 306 SE Application equipment cleaning effectiveness. Report No BF-17/19-01 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
Section B3: Efficacy Data and Information							
KCP 3.2/01	Chermuła Ł.	2018	Efficacy evaluation of FLD-HER 306 SE against broad-leaved weeds in maize; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S18-03531-01 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/02	Chermuła Ł.	2018	Efficacy evaluation of FLD-HER 306 SE against broad-leaved weeds in maize; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S18-03519-01 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.2/03	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02939-01 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/04	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02939-02 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/05	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02939-03 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/06	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02939-04 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.2/07	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02939-05 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/08	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02939-06 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/09	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02939-07 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/10	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in maize. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02939-08 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.2/11	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S18-03519-02 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/12	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-14 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/13	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-15 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/14	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-16 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.2/15	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-17 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/16	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-18 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/17	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in spring wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-19 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/18	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-03517-02 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.2/19	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-01 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/20	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-02 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/21	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-03 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/22	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-04 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.2/23	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-05 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/24	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-06 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/25	Głowacki G.	2019	Determination of Efficacy of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) against dicotyledonous weeds in winter wheat. OUTDOOR.2019; Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02940-07 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/26	Jaczak K.	2019	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in winter wheat. OUTDOOR.2019; Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18055 PL1 F GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.2/27	Jatczak K.	2019	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in spring wheat. OUTDOOR.2019; Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18056 PL2 F GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/28	Jatczak K.	2019	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in maize. OUTDOOR.2019; Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18057 PL1 F GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/29	Jatczak K.	2019	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in maize. OUTDOOR.2019; Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18057 PL2 F GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/30	Katulski B.	2018	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in winter wheat. SGS Polska Sp. z o.o., Poland; Report No.: Pestila_2018—S_001 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/31	Katulski B.	2018	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in spring wheat. SGS Polska Sp. z o.o., Poland; Report No.: Pestila_2018—S_002 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.2/32	Katulski B.	2018	Field study to evaluate the efficacy of FLD-HER 306 SE when applied in spring for the control of weeds in maize. SGS Polska Sp. z o.o., Poland; Report No.: Pestila_2018—S_008 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/01	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in maize. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02932-01 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/02	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in maize. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02932-02 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/03	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in maize. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02932-03 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/04	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in maize. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02932-04 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.4/05	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-01 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/06	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-02 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/07	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-03 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/08	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-04 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/09	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-05 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.4/10	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter triticale. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-11 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/11	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter triticale. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-12 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/12	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter triticale. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-13 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/13	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter triticale. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-14 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/14	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter rye. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-15 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.4/15	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter rye. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-16 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/16	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter rye. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-17 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/17	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter rye. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-18 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/18	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring barley. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-20 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/19	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring barley. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-21 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.4/20	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring barley. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-22 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/21	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring barley. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-23 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/22	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-24 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/23	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-25 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/24	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-26 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.4/25	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in spring wheat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-27 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/26	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in common oat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-29 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/27	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in common oat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-30 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/28	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in common oat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-31 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/29	Głowacki G.	2018	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in common oat. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S19-02943-32 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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 3.4/30	Jatczak K.	2018	Field study to evaluate the selectivity of FLD-HER 306 SE when applied in winter barley. Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18058 PL1 F GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/31	Jatczak K.	2018	Field study to evaluate the selectivity of FLD-HER 306 SE when applied in winter barley. Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18058 PL2 F GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/32	Jatczak K.	2018	Field study to evaluate the selectivity of FLD-HER 306 SE when applied in maize. Anadiag S.A. Oddział w Polsce, Poland; Report No.: PL 18059 PL1 F GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/33	Głowacki G.	2019	Evaluation of the selectivity of FLD-HER 306 SE (florasulam 6,25 g/l + 2,4-D 300 g/l) used post-emergence in winter barley. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S19-02943-19 GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
Section B5: Analytical Methods							
KCP 5.1.1/01	Zajac S.	2019	FLD-HER 306 SE. Determination of active substances content in preparation in COEX bottle. Stage 1: Determination of active substances content in initial preparation Report No 007/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 5.1.1/02	Zajac S.	2019	FLD-HER 306 SE. Determination of active substances content in prepa-ration in COEX bottle. Stage 3: Determination of active substances content in preparation stored at temperature 54±2°C for 14 days. Report No 007/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 5.1.2/01	Gutowska I.	2019	Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation. Report No BA-21/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 5.1.2/02	Gutowska I.	2020	FLD-HER 306 SE 2,4-D 300 g/L + Florasulam 6.25 g/L Determination Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation after accelerate storage. Report No BA-09/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 5.1.2/03	Grodowska K.	2020	GC method for determination of dioxins and furans in FLD-HER 306 SE Report No RVM/2020/53 Selvita Services Sp. z o.o. GLP Yes Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 5.1.2/04	Pstuś J.	2020	Work Progress Report - Development of analytical method for determination of tetra-through octa-chlorinated dioxins and furans by isotope dilution for analysis in Florasulam/2,4-D formulation. Report No REP_20200311_SSV_MWU_Pestila_dioksyny_i_furany_R01v1 Selvita Services Sp. z o.o. GLP: Y Published: N	N	N	-	Pestila*
KCP 5.2-01a (filed as KCP 10.2-01a)	Świstak M.	2019	Validation of analytical method for the determination of test item FLD-HER 306 SE in media for breeding aquatic organisms and in deionized water. Study code: 0005/0067/FA SORBOLAB Research Laboratory LLC, Poznań, Poland GLP: Yes Published: no	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 5.2-01b (filed as KCP 10.2-01b)	Świstak M.	2019	Validation of analytical method for the determination of test item FLD-HER 306 SE in media for breeding aquatic. Study code: 0005/0088/FA SORBOLAB Research Laboratory LLC, Poznań, Poland GLP: Yes Published: no	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 5.2-02 (filed as KCP 10.3-02)	Świstak M.	2019	Validation of analytical method for the determination of test item FLD-HER 306 SE in 50% sucrose solution. Study code: 0005/0074/FA SORBOLAB Research Laboratory LLC, Poznań, Poland GLP: Yes Published: no	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 5.2-03 (filed as KCP 10.4-03)	Świstak M.	2019	Validation of analytical method for the determination of test item FLD-HER 306 SE in soil for breeding earthworms (E. Fetida). Study code: 0005/0079/FA SORBOLAB Research Laboratory LLC, Poznań, Poland GLP: Yes Published: no	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
Section B8: Environmental Fate							
KCP 9.2.4.1/01	Tabor E	2020	FLD-HER 306 SE Calculation of predicted environmental concentrations of 2,4-D and florasulam in groundwater using the FOCUS groundwater scenarios (FOCUS PEARL, FOCUS PELMO) Company Report No: EST/4/2020 Source: ESTICON Tabor Sp.j., Poland GLP: no Published: no	N	N	Not relevant	Pestila*
KCP 9.2.5/01	Tabor E	2020	FLD-HER 306 SE Calculation of Predicted Environmental Concentrations of 2,4-S and florasulam in surface water using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/5/2020 Source: ESTICON Tabor Sp.j., Poland GLP: no Published: no	N	N	Not relevant	Pestila*
Section B9: Ecotoxicology							
KCP 10.2.1.2/01		1989	Results of the harmful effects of selected water pollutants (anilines, phenols, aliphatic compounds) to <i>Daphnia magna</i> Wat. Res. Vol. 23, No. 4, pp. 495-499, 1989 GLP: N Published: Y	Y	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 10.2.1.2/02	Woźniak A	2019	Daphnia acute immobilization test according to OECD 202 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0068/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.2.1.3/01	Kühn, R. <i>et al.</i>	1989	Toxicity of nine benchmark chemicals to <i>Skeletonema costatum</i> , a marine diatom Environmental Toxicology and Chemistry, Vol. 8, pp. 451-455, 1989 GLP: N Published: Y	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.2.1.3/02	Cowgill, U.M. <i>et al.</i>	1990	Results of the harmful effects of water pollutants to green algae (<i>Scenedesmus subspicatus</i>) in the cell multiplication inhibition test. Water Research, Vol 24 (1): 31-38 GLP: N Published: Y	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.2.1.3/03	Woźniak A	2019	Freshwater algae growth inhibition test according to OECD No 201 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0069/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.2.1.4/01	Woźniak A	2019	<i>Lemna gibba</i> growth inhibition test according to OECD 221 SORBBOLAB Research Laboratory LLC Study code: 0005/0070/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.2.1.4/02	Woźniak A	2019	Water-sediment <i>Myriophyllum spicatum</i> toxicity test according to OECD 239 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0071/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 10.3.1.1.1/01	Orzechowska U	2019	Honeybees, Acute Oral Toxicity Test according to OECD 213 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0072/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.3.1.1.2/01	Orzechowska U	2019	Honeybees, Acute Contact Toxicity Test according to OECD 214 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0073/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.3.1.2/01	Orzechowska U	2019	Honey Bee, Chronic Oral Toxicity Test according to OECD 245 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0075/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.3.1.4/01	Orzechowska U	2019	Chronic Toxicity Test for Honey Bee Larvae according to OECD GD 239 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0076/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.3.2.2/01	Kręglewska M	2019	Extended laboratory test (Tier2) for the impact assessment on the parasitic wasp <i>Aphidius rhopalosiphi</i> ; SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0078/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.3.2.2/02	Kręglewska M	2019	Extended laboratory test (Tier2) for evaluating the effects on the predatory mites <i>Typhlodromus pyri</i> (Scheuten) SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0077/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 10.3.2.2/03	Rovetto I	2019	Effects of FLD-HER 306 SE (florasulam 6.5 g/L + 2,4-D-etexyl 297.5 g/L) on <i>Coccinella septempunctata</i> in the laboratory – Extended laboratory test – Year 2019 SAGEA Centro di Saggio s.r.l. Study code: 1075-1075HSAG19/r GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.3.2.2/04	Rovetto I	2019	Effects of FLD-HER 306 SE (florasulam 6.5 g/L + 2,4-D-etexyl 297.5 g/L) on <i>Coccinella septempunctata</i> in the laboratory – Extended laboratory test – Year 2019 SAGEA Centro di Saggio s.r.l. Study code: 1074-1074HSAG19/r GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.4.1.1/01	Woźniak A	2019	Earthworm reproduction test according to OECD 222 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0080/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.5/01	Parma P	2019	Study of impact on soil microorganisms - nitrogen transformation according OECD 216 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0083/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 10.6.2/01	Parma P	2019	Seedling emergence and seedling growth test according to OECD 208 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0081/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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 10.6.2/02	Parma P	2019	Vegetative Vigour Test according to OECD 227 SORBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0082/E GLP: Y Published: N	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

* Pestila Spółka z ograniczoną odpowiedzialnością.

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
-	-	-	-	-	-	-	-

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
-	-	-	-	-	-	-	-

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
-	-	-	-	-	-	-	-