

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: K-300 SL-RR

Product name(s): FAWORYT 300 SL

Chemical active substance:

Clopyralid, 300 g/l

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT – Art. 43

(Renewal of authorisation)

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2021

Correction: 02/2022

MS Finalisation date: 07/2022; 10/2022

Version history

When	What
December 2021	dRR version 1 submitted by applicant
February 2022	Section updated by a 3-year storage stability study
July 2022	zRMS first assessment
October 2022	Final Registration Report

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This documentation has been submitted for the renewal of the authorisation of a plant protection product Faworyt 300 SL (according to the Article 43 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009).

This documentation is submitted in order to meet legal requirements resulting from renewing the approval of the active substance clopyralid in EU (Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021) which is assessment of a plant protection product with the trade name FAWORYT 300 SL in terms of risks to human and animal health and to the impact on the environment.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: CIECH Sarzyna S.A.
Address: ul. Chemików 1, 37-310 Nowa Sarzyna, Poland
Name contact: xxxx
Tel.no. contact xxxx
Email contact: xxxx

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Active substance

Clopyralid (EU agreed minimum purity) min. 950 g/kg

No impurities of toxicological/ ecotoxicological concern are identified in the active substance.
Information relating to the active substance and impurities is confidential information and therefore all details are included in Part C (confidential information).

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: FAWORYT 300 SL

Company code number: K-300 SL-RR

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Clopyralid Chemical IUPAC name : 3,6-dichloropyridine-2-carboxylic acid	300 g/L (pure)	285 – 315 g/L	309.3 g/L (technical)	26.6 % w/w (technical)
Clopyralid-olamine:	395,5 g/L (pure)	380,5 – 410,5 g/L	407.7 g/L (technical)	35.1 % w/w (technical)

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers that is min. 97%

** Based on the density of the formulation = 1.160 g/ml (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Not applicable No safener was used in formulation	-	-	-	-

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Not applicable. Non relevant impurities were identified EU level assessment.	-

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on active substance

Type	Name/Code Number
ISO common name	Clopyralid
CAS No.	1702-17-6
EC No.	216-935-4
CIPAC No.	455

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Table 1.4-5: Information on safeners/ synergists / co-formulant

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Soluble concentrate SL

1.6 Function (KCP 1.6)

Herbicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

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 bright yellow liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature above of 650 °C. In aqueous solution, it has a pH value around 8.5 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 that a shelf life of at least 2 3 years at ambient temperature has to be expected when stored in *high density polyethylene (HDPE) bottles*.

Its technical characteristics are acceptable for a SL formulation.

The intended concentration of use is 0.1% to 0.2%.

~~The report on the three year storage period of the preparation will be completed and presented in April/May 2022.~~

In February the Applicant received the report on the three year storage of the product Faworyt 300 SL. The results are described in point 2.7.5 below.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	EEC A.14 and UN Recommendations	Not explosive	None
Oxidising properties	UN Recommendations Screening Procedure	Not oxidizing	None
Flammability	--	Not applicable for SL-formulation	--
Flash point	--	Not applicable. The product is water solution (contains about 60% of water) and does not contain flammable solvents	--
Auto-flammability	EEC A.15	Self-ignition temperature > 650 °C	None
pH	CIPAC MT 75.3	pH = 9.17 (neat formulation) pH = 8.49 (1% in distilled water)	None
Viscosity	OECD 114	Kinematic viscosity 4.46 mm ² /s at 40 °C	None
Surface tension	EEC A.5	undiluted = 25.2 mN/m; 0,2 % concentration = 37.2 mN/m	None
Relative density	CIPAC MT 3.3	1.156 g/mL at 20 °C	None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Risk and safety phrases relevant for this section: none

Compliance with FAO specifications:

The product FAWORYT 300 SL complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Colour and physical state (KCP 2.1)	OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	Homogenous and transparent bright straw-coloured liquid of characteristic odour	Y	Al Amin I., 2011 Report No. BF-23/11-01	Previously assessed
	OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	Transparent and homogenous bright yellow liquid of characteristic odour	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted
Explosive properties (KCP 2.2.1)	Not applicable. Faworyt 300 SL is liquid contains about 60% of water, the individual components of the preparation i.e. the active substance and the co-formulants do not contain any groups associated with explosive properties in their structures what is confirmed in the MSDS for all of the co-formulants and active substance. Therefore, it could be assumed that the product Faworyt 300 SL do not possess explosive properties.					Accepted
Oxidizing properties (KCP 2.2.2)	Not applicable. Faworyt 300 SL is liquid (water soluble concentrate), the individual components of the preparation i.e. the active substance and the co-formulants do not contain any groups associated with oxidising properties in their structures what is confirmed in the MSDS for all of the co-formulants and active substance. Therefore, it could be assumed that the product Faworyt 300 SL do not possess oxidising properties.					Accepted
Flash point (KCP 2.3.1)	Not applicable. The product is water solution (contains about 60% of water) and does not contain any flammable components.					Accepted
Flammability (KCP 2.3.2)			Not required for liquid formulations			Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Self-heating Auto-Ignition (KCP 2.3.3)	EC No. 440/2008 Method A.15. DIN 51794 (2003)	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	The test item Faworyt 300 SL does not undergo auto-ignition up to a temperature of 650 °C according to the Regulation EC No. 440/2008 Method A.15. Auto-Ignition Temperature (Liquids and Gases)	Y	Flasińska, P., 2019 Report No. BC-04/19	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	Since the pH value ranged from 4 to 10, the acidity or alkalinity test (CIPAC MT 31 or 191) was not performed.					
	CIPAC MT 75.3	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	pH value (neat test item): 8.72	Y	Al Amin I., 2011 Report No. BF-23/11-02	Previously assessed
	CIPAC MT 75.3	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	pH value (neat test item): 9.17	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	pH value (1% aqueous dilution): 7.95	Y	Al Amin I., 2011 Report No. BF-23/11-02	Previously assessed

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
	CIPAC MT 75.3	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	pH value (1% aqueous dilution): 8.49	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted
Viscosity (KCP 2.5.1)	CIPAC MT 192, OECD No. 114	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	Viscosity of liquids by Ubbelohde capillary viscometer Kinematic viscosity: 8.66 mm ² /s at 20°C 4.46 mm ² /s at 40°C	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted
Surface tension (KCP 2.5.2)	EC A.5 OECD No.115	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	undiluted = 25.2 mN/m at 25°C	Y	Lewandowska M, 2011 Report No.: BS-03/11	Previously assessed
	EC A.5 OECD No.115	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	test item aqueous solutions at 0.2 % v/v = 37.2 mN/m at 20°C	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted RMS Comments: Active surface substance

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Relative density (KCP 2.6.1)	CIPAC MT 3.2, EC 440/2008 No. A.3	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	1.164 g/mL at 20°C	Y	Al Amin I., 2011 Report No. BF-23/11-03	Previously assessed
	CIPAC MT 3.2, EC 440/2008 No. A.3	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	1.156 g/mL at 20°C	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted
Bulk density (KCP 2.6.2)	Not required for liquid formulations					Statement accepted
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 CIPAC MT 3 CIPAC MT 75	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	<p>After storage at 54°C for 14 days the colour of product darkened slightly, no secretion of any solid particles and oily components was observed.</p> <p>Initial content of clopyralid: 311.5 g/L After storage content of clopyralid: 313.3 g/L</p> <p>No changes in pH value and density were noted, i.e.: <u>pH value (undiluted product)</u> before storage: pH = 8.4 after storage: pH = 8.3 <u>density</u> before & after storage: $D_{4}^{20} = 1.165$</p> <p>The measurements confirm the stability of the formulation.</p>	N	Paleń P., 2011 Report No.: TS/7/11	Previously assessed

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability /comments																										
Storage Stability after 14 days at 54° C (KCP 2.7.1)		Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	<table border="1"> <thead> <tr> <th data-bbox="750 389 927 416">Test / Type</th> <th data-bbox="927 389 1111 416">Methods</th> <th colspan="2" data-bbox="1111 389 1644 416">Findings</th> </tr> <tr> <td></td> <td></td> <th data-bbox="1111 416 1384 448">Initial preparation</th> <th data-bbox="1384 416 1644 448">After accelerated storage</th> </tr> </thead> <tbody> <tr> <td data-bbox="750 485 927 667">Physical state colour and odour</td> <td data-bbox="927 485 1111 667">Visual inspection, nasal inhalation</td> <td data-bbox="1111 485 1384 667">Transparent and homogenous bright yellow liquid of characteristic odour</td> <td data-bbox="1384 485 1644 667">Transparent and homogenous bright yellow liquid of characteristic odour</td> </tr> <tr> <td data-bbox="750 667 927 699">pH undiluted</td> <td data-bbox="927 667 1111 699" rowspan="2">CIPAC MT 75.3</td> <td data-bbox="1111 667 1384 699">9.17</td> <td data-bbox="1384 667 1644 699">9.03</td> </tr> <tr> <td data-bbox="750 699 927 762">pH 1 % solution</td> <td data-bbox="1111 699 1384 762">8.49</td> <td data-bbox="1384 699 1644 762">8.50</td> </tr> <tr> <td data-bbox="750 762 927 858">Dilution stability</td> <td data-bbox="927 762 1111 858">CIPAC MT 41.1</td> <td data-bbox="1111 762 1384 858">homogenous and transparent</td> <td data-bbox="1384 762 1644 858">homogenous and transparent</td> </tr> <tr> <td data-bbox="750 858 927 922">Active ingredient</td> <td data-bbox="927 858 1111 922">HPLC</td> <td data-bbox="1111 858 1384 922">Clopyralid 25,66 % (296,6 g/l)</td> <td data-bbox="1384 858 1644 922">Clopyralid 25,11 % (290,3 g/l)</td> </tr> </tbody> </table>	Test / Type	Methods	Findings				Initial preparation	After accelerated storage	Physical state colour and odour	Visual inspection, nasal inhalation	Transparent and homogenous bright yellow liquid of characteristic odour	Transparent and homogenous bright yellow liquid of characteristic odour	pH undiluted	CIPAC MT 75.3	9.17	9.03	pH 1 % solution	8.49	8.50	Dilution stability	CIPAC MT 41.1	homogenous and transparent	homogenous and transparent	Active ingredient	HPLC	Clopyralid 25,66 % (296,6 g/l)	Clopyralid 25,11 % (290,3 g/l)	Initial preparation	After accelerated storage	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted
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Active ingredient	HPLC	Clopyralid 25,66 % (296,6 g/l)	Clopyralid 25,11 % (290,3 g/l)																																
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not required as the formulation was stable at 54°C after 14 days								Statement accepted																										
Minimum content after heat stability testing (KCP 2.7.3)	Not required as the formulation was stable at 54°C after 14 days. The a.s. content after the heat stability test has not decreased by more than 5% of the initial content (see point IIIA 2.7.1).								Accepted																										

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 3 CIPAC MT 75	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	After storage at 0°C for 7 days the colour of product has not changed, no secretion of any solid particles and oily components was observed. Initial content of clopyralid : 311.5 g/L After storage content of clopyralid: 313.5 g/L No changes in pH value and density were noted, i.e.: <u>pH value (undiluted product)</u> before & after storage: pH = 8.4 <u>density</u> before & after storage: D ²⁰ ₄ = 1.165 The measurements confirm the stability of the formulation.	N	Palań P.,2011 Report No.: TS/6/11	Previously assessed
	CIPAC MT 39.3	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	After 7 days at 0 ± 2°C: The preparation immediately after storage at 0 °C, at room temperature and after 24 hours at room temperature was transparent and homogenous liquid.	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Ambient temperature shelf life (KCP 2.7.5)	Technical Monograph no 17 CIPAC MT 3 CIPAC MT 75 CIPAC MT 41 CIPAC MT 47	Faworyt 300 SL containing 299.2 g/L of clopyralid Batch No.: 1 Production date: 03.2009	No changes in appearance both before and after storage for 3 years were noted. Initial content of a.s.: 299.2 g/L After storage: 302 g/L No significant changes in measured quality parameters were noted, i.e.: <u>pH value (1% (w/v))</u> before storage: 5.8 after storage: 5.7 <u>density</u> before storage: D ²⁰ ₄ = 1.178 after storage: D ²⁰ ₄ = 1.177 <u>dilution stability (5% (v/v), CIPAC standard water C, 20°C)</u> before & after storage: no separated material after 18 hrs <u>persistent foaming (1% (w/v), CIPAC standard water C, 20°C)</u> before storage: 9 and 5 mL (respectively after 1 and 5 minute) after storage: 15 and 13 mL (respectively after 1 and 5 minute) The product is stable for 3 years. The product was stored in package made of HDPE. After storage no deformation of package was observed.	N	Palań P.,2012 Report No.: TS/3/12	Previously assessed

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability /comments	
Ambient temperature shelf life (KCP 2.7.5)	Technical Monograph no 17	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	Test Type	Methods	Findings		Y	Enzo Arevalo,2021 Report No. BF-05/19 – Part II	Accepted Comment: All results are accepted. Product is stable after ambient temperature shelf life stability test which was stored in HDPE bottles. All validation parameters meet the requirements of the guidance document SAN-CO/3030/99 rev. 4 and rev. 5. The method is acceptable.	
					Initial preparation	After two years of storage				
			Physical state colour and odour	Visual inspection, nasal inhalation	Transparent and homogenous bright yellow liquid of characteristic odour	Transparent and homogenous bright yellow liquid of characteristic odour				
			pH	Undiluted	CIPAC	9.17				8.94
				1% solution	MT 75.3	8.49				8.44
			Dilution stability	CIPAC MT 41.1	homogenous and transparent	homogenous and transparent				
			Package stability	CropLife International Technical Monograph No. 17.	1 L HDPE	Stable, 1 L HDPE				
Active ingredient	HPLC/UV-DAD	Clopyralid 25.66% (296.6 g/l)	Clopyralid 25.37 % (293.3 g/l)							

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability /comments																																							
Ambient temperature shelf life (KCP 2.7.5)	Technical Monograph no 17	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	<table border="1"> <thead> <tr> <th rowspan="2">Test Type</th> <th rowspan="2">Methods</th> <th colspan="3">Findings</th> </tr> <tr> <th>Initial preparation</th> <th>After two years of storage</th> <th>After three years of storage</th> </tr> </thead> <tbody> <tr> <td>Physical state colour and odour</td> <td>Visual inspection, nasal inhalation</td> <td>Transparent and homogenous bright yellow liquid of characteristic odour</td> <td>Transparent and homogenous bright yellow liquid of characteristic odour</td> <td>Transparent and homogenous bright yellow liquid of characteristic odour</td> </tr> <tr> <td rowspan="2">pH</td> <td>Undiluted</td> <td>CIPAC</td> <td>9.17</td> <td>8.94</td> <td>9.13</td> </tr> <tr> <td>1% solut.</td> <td>MT 75.3</td> <td>8.49</td> <td>8.44</td> <td>8.71</td> </tr> <tr> <td>Dilution stability</td> <td>CIPAC MT 41.1</td> <td>homogenous and transparent</td> <td>homogenous and transparent</td> <td>homogenous and transparent</td> </tr> <tr> <td>Package stability</td> <td>CropLife International Technical Monograph No. 17.</td> <td>1 L HDPE</td> <td>Stable, 1 L HDPE</td> <td>Stable, 1 L HDPE</td> </tr> <tr> <td>Active ingredient</td> <td>HPLC/UV-DAD</td> <td>Clopyralid 25.66% (296.6 g/l)</td> <td>Clopyralid 25.37 % (293.3 g/l)</td> <td>Clopyralid 26.18 % (302.66 g/l)</td> </tr> </tbody> </table>					Test Type	Methods	Findings			Initial preparation	After two years of storage	After three years of storage	Physical state colour and odour	Visual inspection, nasal inhalation	Transparent and homogenous bright yellow liquid of characteristic odour	Transparent and homogenous bright yellow liquid of characteristic odour	Transparent and homogenous bright yellow liquid of characteristic odour	pH	Undiluted	CIPAC	9.17	8.94	9.13	1% solut.	MT 75.3	8.49	8.44	8.71	Dilution stability	CIPAC MT 41.1	homogenous and transparent	homogenous and transparent	homogenous and transparent	Package stability	CropLife International Technical Monograph No. 17.	1 L HDPE	Stable, 1 L HDPE	Stable, 1 L HDPE	Active ingredient	HPLC/UV-DAD	Clopyralid 25.66% (296.6 g/l)	Clopyralid 25.37 % (293.3 g/l)	Clopyralid 26.18 % (302.66 g/l)	Y	Enzo Arevalo,2021 Report No. BF-05/19 – Part III	Accepted Comment: All results are accepted. Product is stable after ambient temperature shelf life stability test which was stored in HDPE bottles. All validation parameters meet the requirements of the guidance document SAN-CO/3030/99 rev. 4 and rev.5 The method is acceptable.
Test Type	Methods	Findings																																															
		Initial preparation	After two years of storage	After three years of storage																																													
Physical state colour and odour	Visual inspection, nasal inhalation	Transparent and homogenous bright yellow liquid of characteristic odour	Transparent and homogenous bright yellow liquid of characteristic odour	Transparent and homogenous bright yellow liquid of characteristic odour																																													
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Ambient temperature shelf life (KCP 2.7.5)	A three year room temperature storage study is currently underway. The research will be completed in April/May 2022. The report on the three year storage period of the preparation will be submitted imidiately after completion.							-																																									
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable. The shelf life is 3 years.							N/A																																									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Wettability (KCP 2.8.1)	Not required for liquid formulations					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47 and MT 18 (Standard Water C)	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	Volume of foam (1% dilution, CIPAC standard water C) After 10 s: 20 mL After 1, 3 and 12 min: 0 mL	N	Filip W, 2011 Report No. HC1/W60/11	Previously assessed
	CIPAC MT 47.3 and MT 18 (Standard Water D)	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	Foam after 1 and 12 min.: 0.1% concentration – 6 ml of foam after 1 min and 2 ml after 12 min 0.2% concentration – 11 ml of foam after 1 min and 8 ml after 12 min	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted
Suspensibility (KCP 2.8.3.1)			Not required for SL formulations			Statement accepted
Spontaneity of dispersion (KCP 2.8.3.2)			Not required for SL formulations			Statement accepted
Dispersion stability (KCP 2.8.3.3)			Not required for SL formulations			Statement accepted
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41.1 and MT 18 (Standard Water D)	Faworyt 300 SL containing 311.5 g/L of clopyralid Batch No.: 1 Production date: 03.2011	After 18 hours at 20 ± 2°C for the 5.0 % v/v test item aqueous solutions: The solution was clear and there was no any separated sediment.	N	Filip W, 2011 Report No. HC1/W61/11	Previously assessed

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
	CIPAC MT 41.1 and MT 18 (Standard Water D)	Faworyt 300 SL containing 302.7 g/L of clopyralid Batch No.: 201805002 Production date: 16.05.2018	After 24 hours at 30 ± 2°C for the 1.0 % v/v test item aqueous solutions: no visual separation of solid or liquid material, nor changes in its physical state. Sample was homogenous and transparent.	Y	Al Amin I., 2019 Report No. BF-05/19	Accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)			Not required for SL formulations			Statement accepted
Wet sieve test (KCP 2.8.5.1.2)			Not required for SL formulations			Statement accepted
Dust content (KCP 2.8.5.2.1)			Not required for SL formulations			Statement accepted
Particle size of dust (KCP 2.8.5.2.2)			Not required for SL formulations			Statement accepted
Attrition (KCP 2.8.5.3)			Not required for SL formulations			Statement accepted
Hardness and integrity (KCP 2.8.5.4)			Not required for SL formulations			Statement accepted
Emulsifiability (KCP 2.8.6.1)			Not required for SL formulations			Statement accepted
Emulsion stability (KCP 2.8.6.2)			Not required for SL formulations			Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Re-emulsifiability (KCP 2.8.6.3)			Not required for SL formulations			Statement accepted
Flowability (KCP 2.8.7.1)			Not required for SL formulations			Statement accepted
Pourability (KCP 2.8.7.2)			Not required for SL formulations			Statement accepted
Dustability following accelerated storage (KCP 2.8.7.3)			Not required for SL formulations			Statement accepted
Physical compatibility of tank mixes (KCP 2.9.1)			Not applicable. Faworyt 300 SL will not be used with other products.			Statement accepted
Chemical compatibility of tank mixes (KCP 2.9.2)			Not applicable. Faworyt 300 SL will not be used with other products.			Statement accepted
Adhesion to seeds (KCP 2.10.1)			No seed treatment foreseen			Statement accepted
Distribution to seed (KCP 2.10.2)			No seed treatment foreseen			Statement accepted
Other/special studies (KCP 2.11)			No other studies are performed.			Statement accepted

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)

The above information is contained in Part B, Section 7.

4.2 Recommended methods and precautions (KCP 4.2)

Procedures for cleaning application equipment and protective clothing

General statement

All application equipment and contaminated protective clothing should be washed/cleaned with water or a diluted detergent solution and thoroughly rinsed. Care should be taken not to spill the contaminated washings from application equipment into waste water channels. Contaminated cleaning liquids should be disposed of safely according to local regulations.

Application equipment:

Cleaning out of field spraying equipment is an essential part of the recommendations for use of plant protection product.

Procedure:

Empty the spraying equipment completely on the field just sprayed. Remove all filters and nozzles, scrub clean and rinse them with clean water. Put 10 % clean water into tank to cover the agitator. Operate a tank flushing system if fitted. Circulate water through the pump and controls for at least one minute. Drain sprayer, collect washings. Repeat procedure once more. Pump last washing water out through boom feed hoses and pipes. Collect washings. Clean off the outside of the sprayer using minimum water volumes. Collect washings. Replace cleaned nozzles and filters. Collect and put all washings back into the tank and spray out on the field headland, or otherwise safely dispose of them. Ensure the sprayer systems are completely drained before storage. Store Plant Protection Equipment in a properly designated store.

Spray equipment should be cleaned according to normal good agricultural practices, which are considered adequate:

1. Any contamination on the outside of the spraying equipment should be removed by washing with clean water.
2. Rinse inside of tank with clean water and flush through booms and hoses using at least one-tenth of the spray tank volume. Repeat this operation at least three times. After the last time drain tank completely.

Normal procedures should be followed for the cleaning of protective clothing and equipment. Any contamination on the outside of protective equipment should be removed by washing with clean water.

Protective clothing:

All contaminated clothing should be washed/cleaned through with a dilute detergent solution and thoroughly rinsed with clean water.

- Impermeable overalls, boots and face shields should be washed clean and dried.
- Permeable overalls should be laundered after use.
- Disposable overalls and gloves should be washed and disposed of as contaminated waste.
- Gloves and boots should be washed clean, if necessary on the insides as well.

Protective clothing should be washed using clean water separately from the normal work clothing. Clean clothing should be stored away from contaminated clothing in a well-ventilated area separate from the chemical storage area. Damaged or heavily contaminated clothing should be discarded.

Protective equipment for the face and eyes such as face shield and goggles should be cleaned by wiping with a suitable detergent and a wet cloth and left to air dry. It may be necessary to clean this equipment during the application to maintain clear vision. This should be done with a wet cloth and clean water. Damaged eye protection should be discarded.

Protective gloves should be rinsed with water before they are removed from the hands. At the end of each day's use, gloves and rubber boots should be washed with clean water and detergent and left to air dry. Clean items should be stored in a well-ventilated area separate from the chemical storage area. Damaged gloves or boots should be discarded.

Effectiveness of the cleaning procedures

1. Empty the spraying equipment completely on the field just sprayed
2. Dismantle suction, pressure line and nozzle filters and clean thoroughly in water
3. Fill spraying equipment to 10% of tank capacity and stir thoroughly (a rotating cleaning nozzle is recommended)
4. Apply rinsing liquid on the field just sprayed
5. Repeat steps 3 and 4 for a 2nd rinsing
6. Inspect filters again and clean them if visible deposits are present

4.3 Emergency measures in the case of an accident (KCP 4.3)

(a) containment of spillages;

Prevent the product from getting into sewage system, water reservoir, rivers, underground waters and soil. Faworyt 300 SL remains absorb using absorptive materials and collect into tightly closed containers and dispose according to obligatory regulations.

(b) decontamination of areas, vehicles and buildings;

No special procedures.

(c) disposal of damaged packaging, absorbents and other materials;

Damaged packages return to the producer. Other materials dispose according to obligatory regulations. Disposal of wastes into the soil, sewage system and waters is forbidden.

(d) protection of emergency workers and residents, including bystanders;

Standard protection of emergency workers is recommended. Bystanders are recommended to be kept far away from the area.

(e) first aid measures

Skin contact: immediately remove contaminated clothing and footwear. Wash contaminated areas of skin thoroughly with soap and water. Consult a doctor in case of any symptoms of irritation/ allergy.

Contact with the eyes: immediately consult an ophthalmologist. Protect the not-irritated eye, remove contact lenses. Rinse contaminated eyes thoroughly with water for 10-15 minutes. Avoid strong water jet - risk of corneal damage. After rinsing apply sterile dressing.

In case of ingestion: immediately call a doctor , show the packaging or the label. Do not induce vomiting. Rinse mouth thoroughly with water, and then drink plenty of water. Never give anything to eat or drink to an unconscious person.

Respiratory exposure: take the injured person out to fresh air, provide warmth and peace. In case of any worrying symptoms, consult a doctor.

4.4 Packaging and Compatibility with the Preparation (KCP 4.4)

Faworyt 300 SL will be commercially available in HDPE container with a capacity of 100, 250 and 500 mL and also 1, 3, 5, 10, 20 , 60 , 120, 200 and 1000 L.

Table 1.6-1: Packaging information

Type	Description		
	100 mL bottle	250 mL bottle	500 mL bottle
Material:	HDPE	HDPE	HDPE
Shape/size:	round 88 mm high, diameter Ø 45 mm	round 110.7 mm high, diameter Ø 60 mm	cylindrical / Ø 74.0 ± 5 mm, 183,5 ± 10.0 mm high
Opening:	Ø 34.5 ± 2.0 mm	Ø 34,5 ± 1.0 mm	Ø 45 ± 2.0 mm
Closure:	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process
Seal:	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE
Manner of construction	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding
UN/ADR	Compliant with the current UN and ADR requirements for packaging testing.		

Type	Description				
	1 L bottle	3 L canister	5 L canister	10 L canister	20 L canister
Material:	HDPE	HDPE	HDPE	HDPE	HDPE
Shape/size:	cylindrical / Ø 88.5 ± 5 mm, 240 ± 12.0 mm high	rectangular 242 ± 1,5 mm high 161,7 ± 1 mm length 118,5 ± 1 mm width	rectangular 320 ± 16 mm high 186 ± 10 mm length 135 ± 7 mm width	rectangular 376 ± 19 mm high 232 ± 12 mm length 167± 9 mm width	rectangular, 386 ± 20 mm high 290 ± 15 mm length, 248 ± 13 mm width
Opening:	Ø 45 ± 2.0 mm	Ø 47 ± 1.0 mm	Ø 57.3 ± 3 mm	Ø 57.3 ± 3 mm	Ø 49 ± 3 mm
Closure:	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type with an element breakable when opening
Seal:	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/EPE 250/PE
Manner of construction	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding
UN/ADR	Compliant with the current UN and ADR requirements for packaging testing.				

Table 4.4-2: Packaging information for next package type

Type	Description			
	60 L canister	120 L drum	200 L drum	1000 L container (IBC)
Material:	HDPE	HDPE	HDPE	HDPE
Shape/size:	rectangular 641 ± 33 mm high 382 ± 20 mm length 329 ± 17 mm width	cylindrical Ø(d1) 503 mm, Ø(d2) 391 mm, 791 ± 10.0 mm - high	cylindrical Ø(d1) 503 mm, Ø(d2) 391 mm, 791 ± 10.0 mm -high	Cubic 1160 ± 25 mm high 1200 ± 5 mm length 1000 ± 5 mm width
Opening:	Ø max 70 mm	Ø max 70 mm	Ø max 70 mm	Ø max 150 mm
Closure:	screw-on type with an element breakable when opening	screw-on type on the cap is assumed seal	screw-on type on the cap is assumed seal	screw-on type on the cap is assumed seal
Seal:	Seal used but no data on con- struction	Seal used but no data on con- struction	Seal used but no data on con- struction	Seal used but no data on construction
Manner of construction	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding
UN/ADR	Compliant with the current UN and ADR requirements for packaging testing.			

The product is contained and handled in suitable packaging material. The material proposed for use is known from experience to be very resistant to the product chemistry and solvents. The content has no negative effect on packaging integrity.

The above packaging material has been tested and was found to be suitable for the product Faworyt 300 SL. There were no signs of packaging deformation when the packaging containing the product was stored for 3 years at ambient temperature (see point IIIA 2.7.5).

RMS Comments:

Recommended packagings are accepted.

4.5 Procedures for destruction or decontamination of the plant protection product and its packaging (KCP 4.5)

4.5.1. Neutralisation procedures

Do not allow to escape into sewage system or water courses. Do not wash residues into drains or other waterways.

Any chemical treatment at the location of an accidental spillage would be difficult to control in terms of efficiency and safety and is therefore not recommended.

All wastes of the product and its packages should be collected and incinerated.

4.5.2. Controlled incineration

Unwanted amounts of product can be best destroyed by combustion in a licensed incinerator in accordance with the criteria laid down in Directive 94/67/EC of the Council.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1	Al Amin I.	2011	Faworyt 300 SL – Evaluation of appearance Institute of Industrial Organic Chemistry, Poland Report No.: BF-23/11 - 01 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.4	Al Amin I.	2019	Faworyt 300 SL – Part I: Determination of physicochemical properties of the initial, after accelerated and low temperature stosage Institute of Industrial Organic Chemistry, Poland Report No.: BF-05/19 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.2.1	Parobek B	2021	Statement concerning explosives properties of the plant protection product Faworyt 300 SL CIECH Sarzyna S.A. Non GLP Unpublished	N	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.2.2	Parobek B	2021	Statement concerning oxidising properties of the plant protection product Faworyt 300 SL CIECH Sarzyna S.A. Non GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.3.1	Parobek B	2021	Statement concerning flashpoint of the plant protection product Faworyt 300 SL CIECH Sarzyna S.A. Non GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.3.3	Flasińska, P	2019	Faworyt 300 SL – Determination of auto-ignition temperature Institute of Industrial Organic Chemistry, Poland Report No.: BC-04/19 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.4.1 KCP 2.4.2	Al Amin I.	2011	Faworyt 300 SL – Determination of pH Institute of Industrial Organic Chemistry, Poland Report No.: BF-23/11 - 02 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.5.2	Lewandowska M	2011	Faworyt 300 SL – Physicochemical properties study. Determination of surface tension Institute of Industrial Organic Chemistry, Poland Report No.: BS-03/11 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.6.1	Al Amin I.	2011	Faworyt 300 SL – Determination of Relative Density Institute of Industrial Organic Chemistry, Poland Report No.: BF-23/11 - 03 GLP Unpublished	N	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.7.1	Palen P.	2011	Test przyspieszonego starzenia środka ochrony roślin Faworyt 300 SL Zakłady Chemiczne “Organika-Sarzyna” S.A., Poland Report No.: TS/7/11 no GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.7.4	Palen P.	2011	Badanie wpływu niskich temperatur na trwałość środka ochrony roślin Faworyt 300 SL Zakłady Chemiczne “Organika-Sarzyna” S.A., Poland Report No.: TS/6/11 no GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.7.5	Paleń P	2012	Badanie trwałości środka ochrony roślin Faworyt 300 SL po składowaniu przez 3 lata w temperaturze otoczenia Zakłady Chemiczne “Organika-Sarzyna” S.A., Poland Report No.: TS/3/12 no GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.7.5	Enzo Arevalo	2021	Faworyt 300 SL – Part II: Determination of physicochemical properties after two years of storage Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Poland Report No.: BF-05/19 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.7.5	Enzo Arevalo	2022	Faworyt 300 SL – Part III: Determination of physicochemical properties after three years of storage Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Poland Report No.: BF-05/19 GLP Unpublished	N	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.8.2	Filip W	2011	Oznaczenie trwałości piany preparatu Faworyt 300 SL Zakłady Chemiczne “Organika-Sarzyna” S.A., Poland Report No.: HC1/W60/11 no GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.8.4	Filip W	2011	Oznaczenie trwałości roztworu wodnego preparatu Faworyt 300 SL Zakłady Chemiczne “Organika-Sarzyna” S.A., Poland Report No.: HC1/W61/11 no GLP Unpublished	N	CIECH Sarzyna S.A.

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

None.

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	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	Owner
-	-	-	-	-	-

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Active substance

No additional data are submitted for the active substance