

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: **CHR/H/CPD 300SL**

Product name(s):

Major 300SL, Cloe 300SL, ProSto 300SL

Chemical active substance:

Clopyralid, 300 g/L

Central zone

Zonal Rapporteur Member State: Poland

Core assessment

(renewal of authorization)

Applicant: Innvigo sp. z o.o.

Submission date: 12.2021

MS Finalisation date: 11.2022; 03.2023

Version history

When	What
December 2021	New data for CHR/H/CPD based on the renewal of active substance - clopyralid. New data is highlighted in yellow.
November 2022	ZRMS assessment.
March 2023	The final Registration Report

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zRMS comment: No new studies regarding physical-chemical and technical characteristics were submitted during the renewal of the authorisation.
The results of the studies fulfil the requirements of the SANCO/10473/2003 – rev.5.
Commercial packaging remains unchanged (see point 4.1).
No data gaps.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Innvigo sp. z o.o.

Address: Innvigo sp. z o.o.
Al. Jerozolimskie 178
02-486 Warszawa
Poland

Contact point:

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 Clopyralid

According to SANTE/10206/2021 Rev 1 20 May 2021

Clopyralid min. 950 g/kg

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

Trade name: Major 300SL, Cloe 300SL, ProSto 300SL

Company code number:

CHR/H/CPD 300SL

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)
Clopyralid	300 g/L	285 - 315	315,8 g /L

Table 1.4-2: Relevant impurities

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

Relevant impurity	Maximum content (g/L or g/kg)
N/A	N/A

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

Table 1.4-3: Information on Clopyralid

Type	Clopyralid
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)

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

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

Type: Soluble concentrate	[Code: SL]
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1.6 Function (KCP 1.6)

Herbicide in the form of soluble concentrate

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 homogenous, transparent and colourless liquid of a characteristic odour. Its density is 1.148g/ml. It is not explosive and has no oxidising properties. It self-ignites at 460°C. In aqueous solution, it has a pH value around 6.45 –7.30.

The stability data indicate a shelf life of at least 4 years at ambient temperature.

Its technical characteristics are acceptable for an SL formulation.

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

Not required.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not required.

Compliance with FAO specifications:

The product complies with FAO specifications.

At the time of the evaluation, no FAO specification for clopyralid in the form of soluble concentrate was allocated.

Formulation used for tests

Clopyralid 300 SL (CHR/H/CPD)

Active ingredient: Clopyralid 300 g/L

Batch number: 22.01.2014

Producer: PUH “Chemiroł” Sp. z o.o.

Tested material code no. in IPO/BF 24/BF-13/14

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

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Colour, odour and Physical state (KCP 2.1)	EPA Product Properties Test Guidelines OPPTS 830.6302-04, Polish Pharmacopoeia VI Edition (2002).	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	<u>Initial material :</u> Straw-colored, homogenous and transparent liquid of characteristic odour <u>After accelerated storage:</u> Light brown layered liquid of characteristic odour and after mixing homogenous <u>After 1st year of storage:</u> Straw-colored, homogenous and transparent liquid of characteristic odour. <u>After 2nd year of storage:</u> Straw-colored, homogenous and transparent liquid of characteristic odour. <u>After 3rd year of storage:</u> Straw-colored, homogenous and transparent liquid of characteristic odor <u>After 4th year of storage:</u> Straw-colored, homogenous and transparent liquid of characteristic odor	Y	IIIA 2.1/01 Al Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD).Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage. IIIA 2.1/02 Al Amin I., 2015, Clopyralid 300 SL (CHR/H/CPD) Stage II: Determination of the physicochemical properties after the first year of storage IIIA 2.1/03 Al Amin I., 2016 Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage IIIA 2.1/04 Al Amin I., 2017 Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of	The study was assessed during the first authorisation and found acceptable. Accepted.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
					<i>the physicochemical properties after the third year of storage</i> IIIA 2.1/04 Al Amin I., 2018 Clopyralid 300 SL (CHR/H/CPD) Stage V: Determination of the physicochemical properties after the fourth year of storage	
Explosive properties (KCP 2.2.1)			Since high content of water (c.a. 55%) and kind of formulation (SL), CHR/H/CPD is not expected to have explosive properties. Therefore study is not required.			The statements was assessed during the first authorisation and found acceptable. Accepted.
Oxidizing properties (KCP 2.2.2)		Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	Clopyralid 300 SL (CHR/H/CPD) has no oxidizing properties in accordance with test A.21 criteria. Mean pressure rise time for the mixture of Clopyralid 300 SL (CHR/H/CPD) and cellulose, [ms] in all tests the pressure did not reach the criterial values Mean pressure rise time for the mixture of the reference substance (65 % aqueous nitric(V) acid) and cellulose, [ms] $6\,556 \pm 1\,473$		IIIA 2.2.2/01 M.Frączak, 2014, Clopyralid 300 SL (CHR/H/CPD): Determination of oxidizing properties for liquid	The study was assessed during the first authorisation and found acceptable. Accepted.
Flash point (KCP 2.3.1)	Standard PN-EN ISO 2719: 2007 "Determination of flash point – Pensky-Martens closed cup method."	Batch No. 22.01.2014 A.s. content = 304.6g/l	The test substance is placed in the test cup of a Pensky-Martens apparatus and heated to give a constant temperature increase with continuous stirring. An ignition source directed through an opening in the test cup lid at regular temperature intervals with simultaneous interruption of stirring. The lowest temperature at which	Y	IIIA 2.3.1/01 Frączak M., 2014, Clopyralid 300SL CHR/H/CPD: Determination of flash	The study was assessed during the first authorisation

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
		Study code 12/14 Pestanova	the application of the ignition source causes the vapour of the test substance to ignite and propagate over the surface of the liquid was recorded as the flash point at the ambient barometric pressure. Temperature is corrected to standard barometric pressure, by special equation. Test material is boiling at temperature 101 °C. <u>Clopyralid 300 SL (CHR/H/CPD) hasn't flash point in accordance with test A.9. criteria.</u>		<i>point and auto-ignition temperature of liquid.</i>	and found acceptable. Accepted.
Flammability (KCP 2.3.2)			NA			
Auto-flammability	Standard DIN 51794:2003-05 „Prüfung von Mineralölkohlenwasserstoffen. Bestimmung der Zündtemperatur“.	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	The test for determination of the ignition temperature consists in introducing into the opened Erlenmeyer's flask 200 ml (ignition chamber) heated in special apparatus, a small amount of sample using a syringe of pipette and observing if for a given temperature of the chamber walls an ignition appears or not. Changing in many ignition trials the temperature of the chamber walls and amount of a sample according to requirements fixed in Standard Operating Procedure we are looking for the lowest temperature in which an ignition appears. For the temperature of the auto-ignition of the examined substance, it must be assumed the lowest from the lowest values of temperatures, constituting total multiple 5°C at rounding down. Temperature is corrected to thermoelement error. <u>Clopyralid 300 SL (CHR/H/CPD) has the auto-ignition temperature (460 °C) in accordance with test A.15. criteria.</u>	Y	IIIA 2.3.3/01 Fraczak M., 2014, Clopyralid 300 SL (CHR/H/CPD): Determination of flash point and auto-ignition temperature of liquid	The study was assessed during the first authorisation and found acceptable. Accepted.
Self-heating (KCP 2.3.3)			NA			
Acidity or alkalinity and			NA			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
pH (KCP 2.4.1)						
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	Initial preparation: pH of a 1% water emulsion = 7.30 After 14 days at 54°C: pH of a 1% water emulsion = 7.29 After 1 year at 20 °C: pH of a 1% water emulsion = 7.23 After 2 nd year at 20°C: : pH of a 1% water emulsion = 6.72 After 3 rd year at 20°C: : pH of a 1% water emulsion = 6.45 After 4 th year at 20°C: : pH of a 1% water emulsion = 7.12 pH of undiluted (neat) material 6.57 pH of undiluted (neat) material 6.58	Y	IIIA 2.4.2/01 AI Amin I., 2014, <i>Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</i> IIIA 2.4.2/02 AI Amin I., 2015 <i>Clopyralid 300 SL (CHR/H/CPD) Stage II: Determination of the physicochemical properties after the first year of storage</i> IIIA 2.4.2/03 AI Amin I., 2016 <i>Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage</i> IIIA 2.4.2/04 AI Amin I., 2017 <i>Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the</i>	The study was assessed during the first authorisation and found acceptable. Accepted.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
					<p><i>third year of storage</i></p> <p>IIIA 2.4.2/05 AI Amin I., 2017 Annex No.1 to final Report Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</p> <p>IIIA 2.4.2/06 AI Amin I., 2018 Clopyralid 300 SL (CHR/H/CPD) Stage V: Determination of the physicochemical properties after the fourth year of storage</p>	
Kinematic viscosity (KCP 2.5.1)	PN-EN ISO 3104 [OECD 114].	<p>Batch No. 22.01.2014</p> <p>A.s. content = 304.6g/l</p> <p>Study code 12/14</p> <p>Pestanova</p>	<p>9.05 mm²/s.</p> <p>To determine kinematic viscosity, flow time of tested liquid was measured using in this purpose a capillary. The experiment was carried out as following: the measuring capillary was filled with the tested material. The capillary was then fixed to a stand and the whole was thermostated to the test temperature (20°C and 40°C). The temperature was measured by a certified thermometer to the nearest 0.05 °C. When measuring temperature was stabilized, flow time was measured. With a sucking pump, the liquid level in the capillary was moved beyond the measuring mark and allowed to flow under gravity. Flow time was measured to the nearest 0.2 seconds. The test was repeated three times. Results whose differences were not bigger than 0.2 % were taken to consideration.</p> <p>The determined average kinematic viscosity of the prepara-</p>	Y	<p>IIIA 2.5.1/01 AI Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</p> <p>IIIA 2.5.3/02 AI Amin I., 2017, Annex No.2 to final Report Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of</p>	<p>The study was assessed during the first authorisation and found acceptable.</p> <p>The kinematic viscosity is 5.07 mm²/s at 40°C which is below the threshold of 20.5 mm²/s</p>

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			tion at 20 °C temperature was 9.06 mm ² /s and at 40 °C temperature was 5.07 mm ² /s.		<i>physicochemical properties of initial preparation and after accelerated storage</i>	for classification as an aspiration hazard. However, no classification as aspiration hazard is required for the product since no H304 classified components present in the composition. Accepted.
Dynamic viscosity (KCP 2.5.2)	PN-EN ISO 3104 [OECD 114].	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	10.4 mPa·s.	Y	<i>IIIA 2.5.2/01 Al Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</i>	The study was assessed during the first authorisation and found acceptable. Accepted.
Surface tension (KCP 2.5.3)	EEC method A.5. OECD 115 harmonized ring method	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	23.3 mN/m at 20 °C. Diluted at 0.6 kg a.s/hL: The average value of test item surface tension is: 27.94 mN/m.	Y	<i>IIIA 2.5.3/01 Al Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</i>	The study was assessed during the first authorisation and found acceptable. Product is

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
					<i>IIIA 2.5.3/02 AI Amin I., 2017, Annex No.2 to final Report Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</i>	surface active. Accepted.
Relative density (KCP 2.6.1)	CIPAC MT 3.2	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	d= 1.148 at 20 °C.	Y	<i>IIIA 2.6.1/01 AI Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</i>	The study was assessed during the first authorisation and found acceptable. Accepted.
Bulk or tap density (KCP 2.6.2)			N/A			
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46 HPLC	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	A.s. content: Initial: 25.45% [w/w] 303.64 g/L After storage: 25.62% [w/w] 294.12 g/L The determined physicochemical properties of the tested material after accelerated storage test are comparable to the results of the initial material tests.	Y	<i>IIIA 2.7.1/02AI Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</i>	The study was assessed during the first authorisation and found acceptable. Accepted.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments																										
			<table><tr><th rowspan="2">Test Type</th><th rowspan="2">Methods</th><th colspan="2">Findings</th></tr><tr><th>Initial preparation</th><th>After accelerated storage</th></tr><tr><td>Physical state colour and odour</td><td>Visual inspection, nasal inhalation</td><td>Straw-colored liquid of characteristic odor</td><td>Light brown layered liquid of characteristic odor and after mixing homogenous</td></tr><tr><td>pH Determination of 1 % water solution</td><td>CIPAC MT 75.3</td><td>7.30</td><td>7.29</td></tr><tr><td>Dilution stability</td><td>CIPAC MT 41</td><td>At the beginning: turbid solution After 18 h: turbid solution with 1 ml of oil↑</td><td>At the beginning: turbid solution After 18 h: turbid solution with 1 ml of oil↑</td></tr><tr><td>Determination of pourability</td><td>CIPAC MT 148</td><td>Residue: 0.38% Rinsed residue: 0.18%</td><td>Residue: 0.39% Rinsed residue: 0.18%</td></tr><tr><td>Content of active ingredients and relevant impurities</td><td>HPLC</td><td>Clopyralid 26.45% (303.64 g/l)</td><td>Chlopyralid 25.62% (294.12 g/l)</td></tr></table>	Test Type	Methods	Findings		Initial preparation	After accelerated storage	Physical state colour and odour	Visual inspection, nasal inhalation	Straw-colored liquid of characteristic odor	Light brown layered liquid of characteristic odor and after mixing homogenous	pH Determination of 1 % water solution	CIPAC MT 75.3	7.30	7.29	Dilution stability	CIPAC MT 41	At the beginning: turbid solution After 18 h: turbid solution with 1 ml of oil↑	At the beginning: turbid solution After 18 h: turbid solution with 1 ml of oil↑	Determination of pourability	CIPAC MT 148	Residue: 0.38% Rinsed residue: 0.18%	Residue: 0.39% Rinsed residue: 0.18%	Content of active ingredients and relevant impurities	HPLC	Clopyralid 26.45% (303.64 g/l)	Chlopyralid 25.62% (294.12 g/l)			
Test Type	Methods	Findings																														
		Initial preparation	After accelerated storage																													
Physical state colour and odour	Visual inspection, nasal inhalation	Straw-colored liquid of characteristic odor	Light brown layered liquid of characteristic odor and after mixing homogenous																													
pH Determination of 1 % water solution	CIPAC MT 75.3	7.30	7.29																													
Dilution stability	CIPAC MT 41	At the beginning: turbid solution After 18 h: turbid solution with 1 ml of oil↑	At the beginning: turbid solution After 18 h: turbid solution with 1 ml of oil↑																													
Determination of pourability	CIPAC MT 148	Residue: 0.38% Rinsed residue: 0.18%	Residue: 0.39% Rinsed residue: 0.18%																													
Content of active ingredients and relevant impurities	HPLC	Clopyralid 26.45% (303.64 g/l)	Chlopyralid 25.62% (294.12 g/l)																													
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			N/A																													
Minimum content after heat stability testing (KCP 2.7.3)		Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	A.s. content: Initial: 25.45 ± 1.61 % [w/w] After storage: 25.62 ± 0.74 % [w/w]	Y	2.7.3/01 Al Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage	The study was assessed during the first authorisation and found acceptable. Accepted.																										
Effect of low temperatures on stability	CIPAC MT 39.1	Batch No. 22.01.2014 A.s. content	Immediately after storage, at room temperature and after 24 hours homogenous and transparent liquid	Y	IIIA 2.7.4/01 Al Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage	The study was assessed during the first authorisation																										

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments																				
(KCP 2.7.4)		= 304.6g/l Study code 12/14 Pestanova			<i>I: Determination of physicochemical properties of initial preparation and after accelerated storage</i>	and found acceptable. Accepted.																				
Ambient temperature shelf life (KCP 2.7.5)	Standard Operating Procedure SPR/BF/07/b based on Technical Monograph GIFAP No. 17	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	<u>Results after storage for:</u> <table><tr><td>Parameter</td><td>After 1 year</td><td>After 2 year</td><td>After 3 year</td><td>After 4 year</td></tr><tr><td>pH of water emulsion</td><td>7.23</td><td>6.72</td><td>6.45</td><td>7.12</td></tr><tr><td>A.s. content</td><td>25.49% 292.63g/l</td><td>25.60% 293.9g/l</td><td>25.62% 294.12 g/l</td><td>25.63% 294.23 g/l</td></tr><tr><td>Dilution stability</td><td>At the beginning: turbid solution After 18 h: turbid solution with 1 ml of bleeding ↑</td><td>At the beginning: turbid solution After 18 h: turbid solution with 1 ml of bleeding ↑</td><td>At the beginning: turbid solution After 18 h: homogenous solution with 2 ml of bleeding ↑</td><td>At the beginning: turbid solution After 18 h: homogenous solution with 2 ml of bleeding ↑</td></tr></table> <u>Results after 1 year:</u> Straw-colored, homogenous and transparent liquid of characteristic odor Pourability: R _{av.} = 0.38 %, R' _{av.} =0.18%; Package stability: Stable, white, cylindrical HDPE/PA <u>Results after 2 year:</u> Straw-colored, homogenous and transparent liquid of character-	Parameter	After 1 year	After 2 year	After 3 year	After 4 year	pH of water emulsion	7.23	6.72	6.45	7.12	A.s. content	25.49% 292.63g/l	25.60% 293.9g/l	25.62% 294.12 g/l	25.63% 294.23 g/l	Dilution stability	At the beginning: turbid solution After 18 h: turbid solution with 1 ml of bleeding ↑	At the beginning: turbid solution After 18 h: turbid solution with 1 ml of bleeding ↑	At the beginning: turbid solution After 18 h: homogenous solution with 2 ml of bleeding ↑	At the beginning: turbid solution After 18 h: homogenous solution with 2 ml of bleeding ↑	Y	IIIA 2.7.5/01 AI Amin I., 2015, <i>Clopyralid 300 SL (CHR/H/CPD) Stage II: Determination of the physicochemical properties after the first year of storage.</i> IIIA 2.7.5/02 AI Amin I., 2016 <i>Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage</i> IIIA 2.7.5/03 AI Amin 2017, <i>Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage</i> IIIA 2.7.5/04 AI Amin I., 2018 <i>Clopyralid 300 SL (CHR/H/CPD) Stage V: Determination of</i>	The study was assessed during the first authorisation and found acceptable. Accepted.
Parameter	After 1 year	After 2 year	After 3 year	After 4 year																						
pH of water emulsion	7.23	6.72	6.45	7.12																						
A.s. content	25.49% 292.63g/l	25.60% 293.9g/l	25.62% 294.12 g/l	25.63% 294.23 g/l																						
Dilution stability	At the beginning: turbid solution After 18 h: turbid solution with 1 ml of bleeding ↑	At the beginning: turbid solution After 18 h: turbid solution with 1 ml of bleeding ↑	At the beginning: turbid solution After 18 h: homogenous solution with 2 ml of bleeding ↑	At the beginning: turbid solution After 18 h: homogenous solution with 2 ml of bleeding ↑																						

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments								
			istic odor Pourability: $R_{av.} = 0.38 \%$, $R'_{av.}=0.19\%$; Package stability: Stable, white, cylindrical HDPE/PA <u>Results after 3 year:</u> Straw-colored, homogenous and transparent liquid of characteristic odor Pourability: $R_{av.} = 0.44 \%$, $R'_{av.}=0.20\%$; Package stability: Stable, white, cylindrical HDPE/PA <u>Results after 4 year:</u> Straw-colored, homogenous and transparent liquid of characteristic odor Pourability: $R_{av.} = 0.41 \%$, $R'_{av.}=0.21\%$; Package stability: Stable, white, cylindrical HDPE/PA		<i>the physicochemical properties after the fourth year of storage</i>									
Shelf life in months (if less than 2 years) (KCP 2.7.6)			N/A											
Wettability (KCP 2.8.1)			N/A											
Persistence of foaming (KCP 2.8.2)	CIPAC Method MT 47.1 CIPAC Method MT 47.3	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14	Foam volume after: <table border="1"><tr><td>10 sec. [ml]</td><td>1 min. [ml]</td><td>3 min. [ml]</td><td>12 min. [ml]</td></tr><tr><td>4</td><td>0</td><td>0</td><td>0</td></tr></table> It was observed that the CIPAC C water solutions of the preparation formed the following foam volumes:	10 sec. [ml]	1 min. [ml]	3 min. [ml]	12 min. [ml]	4	0	0	0	Y	IIIA 2.8.2/01 AI Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after	The study was assessed during the first authorisation and found acceptable. Accepted.
10 sec. [ml]	1 min. [ml]	3 min. [ml]	12 min. [ml]											
4	0	0	0											

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
		Pestanova	<p>- In the case of 0.3 kg a.i. per hectolitre water: 4 ml after 10 s and 0 ml after 1, 3 and 12 minutes.</p> <p>- In the case of 0.6 kg a.i. per hectolitre water: 8 ml after 10 s, 2 ml after 1 min .and 0 ml after 3 and 12 minutes.</p>		<p><i>accelerated storage</i></p> <p>IIIA 2.8.2/02AI Amin I., 2017, Annex No.2 to final Report Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</p>	
Suspensibility (KCP 2.8.3.1)			N/A			
Spontaneity of dispersion (KCP 2.8.3.2)			N/A			
Dilution stability (KCP 2.8.4)	CIPAC MT 41 CIPAC MT 41.1	<p>Batch No. 22.01.2014</p> <p>A.s. content = 304.6g/l</p> <p>Study code 12/14</p> <p>Pestanova</p>	<p>Initial material:</p> <p>At the beginning: turbid solution After 18 h: turbid solution with 1 ml of oil↑</p> <p>After accelerated storage:</p> <p>At the beginning: turbid solution After 18 h: turbid solution with 1 ml of oil↑</p> <p>After 1st year:</p> <p>At the beginning: turbid solution After 18 h: turbid solution with 1 ml of bleeding ↑</p> <p>After 2nd year:</p> <p>At the beginning: turbid solution</p> <p>After 18 h: turbid solution with 1 ml of bleeding ↑</p>	Y	<p>IIIA 2.8.4/01 AI Amin I., 2014, Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</p> <p>IIIA 2.8.4/02 AI Amin I., 2015, Clopyralid 300 SL (CHR/H/CPD) Stage II: Determination of the physicochemical properties after the</p>	<p>The study was assessed during the first authorisation and found acceptable.</p> <p>Accepted.</p>

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>After 3rd year:</p> <p>At the beginning: turbid solution After 18 h: homogeneous solution with 2 ml of bleeding ↑</p> <p>In order to determine the dilution stability of the preparation a water solution was prepared. To a measuring cylinder containing 50 ml of hard water C, 2.33 ml of the tested material was transferred using 5 ml pipette. The content of the cylinder was diluted by CIPAC</p> <p>C water to a volume of 100 ml (the concentration is 0.6 kg a.i. per hectolitre water).</p> <p>At the beginning: turbid solution After 18 h: homogeneous solution with 2 ml of bleeding ↑</p> <p>After 4th year:</p> <p>At the beginning: turbid solution After 24 h: homogeneous solution with 2 ml of bleeding ↑</p>		<p><i>first year of storage</i></p> <p>IIIA 2.8.4/03 AI Amin I., 2016 <i>Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage</i></p> <p>IIIA 2.8.4/04 AI Amin I., 2017 <i>Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage</i></p> <p>IIIA 2.8.4/05 AI Amin I., 2017 Annex No.2 to final Report <i>Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage</i></p> <p>IIIA 2.8.4/06 AI Amin I., 2018 <i>Clopyralid 300 SL (CHR/H/CPD) Stage V: Determination of the physicochemical properties after the fourth year of storage</i></p>	

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Dry sieve test (KCP 2.8.5.1)			N/A			
Wet sieve test (KCP 2.8.5.2)			N/A			
Particle size distribution (KCP 2.8.6.1)			N/A			
Nominal size range of granules (KCP 2.8.6.2)			N/A			
Dust content (KCP 2.8.6.3)			N/A			
Particle size of dust (KCP 2.8.6.4)			N/A			
Friability and attrition (KCP 2.8.6.5)			N/A			
Emulsifiability (KCP 2.8.7.1)			N/A			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsion stability (KCP 2.8.7.2)			N/A			
Re-emulsifiability (KCP 2.8.7.3)			N/A			
Stability of dilute emulsions (KCP 2.8.7.4)			N/A			
Stability of emulsions (KCP 2.8.7.5)			N/A			
Flowability (KCP 2.8.8.1)			N/A			
Pourability (including rinsed residue) (KCP 2.8.8.2)	CIPAC MT 148	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	Initial material: $R_{av} = 0.38\%$ and $R'_{av} = 0.18\%$. After 14 days at 54 °C: $R_{av} = 0.39\%$ and $R'_{av} = 0.18\%$. After 1 year at ambient temperature: $R_{av} = 0.38\%$ and $R'_{av} = 0.18\%$. After 2 year at ambient temperature: $R_{av} = 0.38\%$ and $R'_{av} = 0.19\%$. After 3 year at ambient temperature: $R_{av} = 0.44\%$ and $R'_{av} = 0.20\%$.	Y	IIIA 2.8.8.2/01 AI Amin I., 2014, <i>Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage</i> IIIA 2.8.8.2/02 AI Amin I., 2015, <i>Clopyralid 300 SL (CHR/H/CPD) Stage</i>	The study was assessed during the first authorisation and found acceptable. Accepted.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			After 4 year at ambient temperature: $R_{av} = 0.41\%$ and $R'_{av} = 0.21\%$.		<p><i>II: Determination of the physicochemical properties after the first year of storage</i></p> <p>IIIA 2.8.8.2/03 AI Amin I., 2016 <i>Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage</i></p> <p>IIIA 2.8.8.2/04 AI Amin I., 2017 <i>Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage</i></p> <p>IIIA 2.8.8.2/05 AI Amin I., 2018 <i>Clopyralid 300 SL (CHR/H/CPD) Stage V: Determination of the physicochemical properties after the fourth year of storage</i></p>	
Dustability following accelerated storage (KCP 2.8.8.3)			N/A			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings			GLP Y/N	Reference	Acceptability / comments
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM E1518	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code 12/14 Pestanova	Physical compatibility of CHR/H/PCR + CHR/H/CPD The tested material was a tank mixture of two preparations CHR/H/PCR and CHR/H/CPD The mixture was prepared in the ratio 0.0234 kg picloram and 0.09 kg clopyralid in 200 litres (200 kg) of CIPAC C water.			Y	IIIA 2.9.1/01 Al Amin I., 2016, <i>CHR/H/PCR + CHR/H/CPD</i> <i>Evaluation the physical and chemical compatibility</i> <i>Study code no. BF-74/16</i> IIIA 2.9.1/02 Al Amin I., 2016, <i>CHR/H/PCR + CHR/H/CPD + CHR/H/MTC</i> <i>Evaluation the physical and chemical compatibility</i> <i>Study code no. BF-75/</i>	The study was assessed during the first authorisation and found acceptable. Accepted.
			Type of test/ Compatibility	Initial mixture	Mixture after 30 min of mixing			
			Physical	homogeneous	homogeneous			
			Physical compatibility of CHR/H/PCR +CHR/H/CPD+CHR/H/MTC The tested material was a tank mixture of three preparations CHR/H/PCR, CHR/H/CPD and CHR/H/MTC. The mixture was prepared in the ratio 0.0234 kg picloram, 0.09 kg clopyralid and 0.750 kg metazachlor in 200 litres (200 kg) of CIPAC C water.					
			Type of test/ Compatibility	Initial mixture	Mixture after 30 min of mixing			
Physical	homogeneous	homogeneous						
Chemical compatibility of tank mixes (KCP 2.9.2)	HPLC	Batch No. 22.01.2014 A.s. content = 304.6g/l Study code	Chemical compatibility of CHR/H/PCR + CHR/H/CPD The tested material was a tank mixture of two preparations CHR/H/PCR and CHR/H/CDP The mixture was prepared in the ratio 0.0234 kg picloram and 0.09 kg clopyralid in 200 litres (200 kg) of CIPAC C water.			Y	IIIA 2.9.2/01 Al Amin I., 2016, <i>CHR/H/PCR + CHR/H/CPD</i> <i>Evaluation the physi-</i>	The study was assessed during the first authorisation and found

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments																		
		12/14 Pestanova	<table><tr><td>Type of test/ Compatibility</td><td>Initial mixture</td><td>Mixture after 30 min of mixing</td></tr><tr><td rowspan="2">Chemical compatibility HPLC</td><td>picloram 0.010%</td><td>picloram 0.011%</td></tr><tr><td>Clopyralid 0.042%</td><td>Clopyralid 0.048%</td></tr></table> Chemical compatibility of CHR/H/PCR+CHR/H/CPD+CHR/H/MTC The tested material was a tank mixture of three preparations CHR/H/PCR, CHR/H/CDP and CHR/H/MTC. The mixture was prepared in the ratio 0.0234 kg picloram, 0.09 kg clopyralid and 0.750 kg metazachlo in 200 litres (200 kg) of CIPAC C water. <table><tr><td>Type of test/ Compatibility</td><td>Initial mixture</td><td>Mixture after 30 min of mixing</td></tr><tr><td rowspan="3">Chemical compatibility HPLC</td><td>picloram 0.010%</td><td>picloram 0.010%</td></tr><tr><td>Clopyralid 0.048%</td><td>Clopyralid 0.042%</td></tr><tr><td>Metazachlor 0.327%</td><td>Metazachlor 0.353%</td></tr></table>	Type of test/ Compatibility	Initial mixture	Mixture after 30 min of mixing	Chemical compatibility HPLC	picloram 0.010%	picloram 0.011%	Clopyralid 0.042%	Clopyralid 0.048%	Type of test/ Compatibility	Initial mixture	Mixture after 30 min of mixing	Chemical compatibility HPLC	picloram 0.010%	picloram 0.010%	Clopyralid 0.048%	Clopyralid 0.042%	Metazachlor 0.327%	Metazachlor 0.353%		cal and chemical compatibility Study code no. BF-74/16 IIIA 2.9.2/02 Al Amin I., 2016, CHR/H/PCR + CHR/H/CPD + CHR/H/MTC Evaluation the physical and chemical compatibility Study code no. BF-75/16	acceptable. Accepted.
Type of test/ Compatibility	Initial mixture	Mixture after 30 min of mixing																						
Chemical compatibility HPLC	picloram 0.010%	picloram 0.011%																						
	Clopyralid 0.042%	Clopyralid 0.048%																						
Type of test/ Compatibility	Initial mixture	Mixture after 30 min of mixing																						
Chemical compatibility HPLC	picloram 0.010%	picloram 0.010%																						
	Clopyralid 0.048%	Clopyralid 0.042%																						
	Metazachlor 0.327%	Metazachlor 0.353%																						
Adhesion to seeds (KCP 2.10.1)			N/A																					
Distribution to seed (KCP 2.10.2)			N/A																					
Miscibility	Not required																							

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.11)						
Dielectric breakdown (KCP 2.12)	Not required					
Corrosion characteristics (KCP 2.13)	Not required					
Container material (KCP 2.14)	Not required					
(KCP 2.15)						

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 Packaging and Compatibility with the Preparation (KCP 4.4)

CHR/H/CPD will be packed in High Density PolyEthylene/ polyamide (HDPE/PA) containers having the size appropriate to hold either 250, 500, 1000, 3000, 5000, and 10000 ml of product, respectively. A description of the packaging and of the corresponding type of cap is given below:

HDPE/PA CONTAINERS

250 ml pack size

Material: HDPE/PA

Type of construction: BOTTLE

Size: 62.5±1 mm/131.3±1 mm

Capacity: 323 ± 5 ml

Weight: 30±1.5g

Type of closure: screw cap with seal

Size of opening: 45.65±3 mm

Material: HDPE/PA

Type of construction: BOTTLE

Size: 59 ± 1 mm/143 ± 1 mm/

Capacity: 275 ml

Weight: 32 ± 2 g

Type of closure: screw cap with seal

Size of opening: 41.7±0.7 mm

500 ml pack size

Material: HDPE/PA

Type of construction: BOTTLE

Size: 69 mm ± 2 mm/186.5 mm ± 2 mm

Capacity: 574 ml

Weight: 45±2g

Type of closure: screw cap with seal

Size of opening: 45.65±3 mm

Material: HDPE/PA

Type of construction: BOTTLE

Size: 74± 1 mm/177 ± 1 mm/

Capacity: 550 ml

Weight: 55 ± 2 g

Type of closure: screw cap with seal

Size of opening: 41.7±0.7 mm

Material: HDPE/PA

Type of construction: BOTTLE

Size: 65 mm/234.8 mm ± 2 mm

Capacity: 500 ml

Weight: 35 g ± 2 g

Type of closure: screw cap with seal

Size of opening: 27.4 mm

1000 ml pack size

Material: HDPE/PA COEX
Type of construction: BOTTLE
Size: 88 mm \pm 2 mm/238 mm \pm 2 mm
Capacity: 1000 ml
Weight: 93g /108g \pm 2 g
Type of closure: screw cap with cutter
Size of opening: 50 mm \pm 2 mm

Material: HDPE/PA
Type of construction: BOTTLE
Size: 248.5 \pm 3 mm/84 \pm 1.5mm
Capacity: 1000 ml
Weight: 60/90/95g \pm 2 g
Type of closure: screw cap with seal
Size of opening: 50 mm \pm 2 mm

Material: HDPE/PA
Type of construction: BOTTLE
Size: 248.5 \pm 3 mm/84 \pm 1.5mm
Capacity: 1000 ml
Weight: 60/90/95g \pm 2 g
Type of closure: screw cap with seal
Size of opening: 50 mm \pm 5 mm

Material: HDPE/PA
Type of construction: BOTTLE
Size: 238 \pm 1 mm/88 \pm 1 mm/
Capacity: 1100 ml
Weight: 92 \pm 2 g
Type of closure: screw cap with seal
Size of opening: 41.7 \pm 0,7 mm

Material: HDPE/PA
Type of construction: BOTTLE
Size: 233.5 \pm 1.5 mm/88.5 \pm 1 mm/
Capacity: 1100 ml
Weight: 92 \pm 2 g
Type of closure: screw cap with seal
Size of opening: 39 mm \pm 2 mm

Material: HDPE/PA
Type of construction: BOTTLE
Size: 84 \pm 1.5 mm/248.5 \pm 3 mm
Capacity: 1000 ml
Weight: 60/90/95 g \pm 2 g
Type of closure: screw cap with seal
Size of opening: 50 mm \pm 3mm

5000 ml pack size
Material: HDPE/PA
Type of construction: CONTAINER
Size: 305mm \pm 5 mm/193 mm \pm 5 mm/142 mm \pm 5 mm
Capacity: 5850 ml \pm 150 ml
Weight: 230 g \pm 10 g
Type of closure: screw cap with seal

Size of opening: 63 mm minimum \pm 5 mm

Material: HDPE/PA

Type of construction: BOTTLE

Size: 193 ± 3 / 142 ± 5 mm/ $320 \text{ mm} \pm 5 \text{ mm}$

Capacity: 5500 ml

Weight: $245 \pm 12 \text{ g}$

Type of closure: screw cap with seal

Size of opening: $63,3 \pm 3 \text{ mm}$

Material: HDPE/PA

Type of construction: CANNISTER

Size: $313 \pm 5 \text{ mm}$ / 190 ± 3 / $140 \pm 5 \text{ mm}$

Capacity: 5000 ml

Weight: $60/90/95 \text{ g} \pm 5 \text{ g}$

Type of closure: screw cap with seal

Size of opening: $50 \text{ mm} \pm 3 \text{ mm}$

10000 ml pack size

Material: HDPE/PA

Type of construction: CONTAINER

Size: 305 mm / 193 mm / $142 \text{ mm} \pm 5 \text{ mm}$

Capacity: $10000 \text{ ml} \pm 150 \text{ ml}$

Weight: $220 \text{ g} \pm 10 \text{ g}$

Type of closure: screw cap with seal

Size of opening: 63 mm minimum \pm 5 mm

Appendix 1 *Lists of data considered in support of the evaluation*

List of data submitted by the applicant and relied on

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 2.1/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.1/02	Al Amin I.	2015	Clopyralid 300 SL (CHR/H/CPD) Stage II: Determination of the physicochemical properties after the first year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.1/03	Al Amin I.	2016	Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 2.1/04	Al Amin I.	2017	Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł
KCP 2.1/04	Al Amin I.	2018	Clopyralid 300 SL (CHR/H/CPD) Stage V: Determination of the physicochemical properties after the fourth year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł
KCP 2.2.2/01	Frączak M.	2014	Clopyralid 300 SL (CHR/H/CPD): Determination of oxidizing properties for liquid Institute of Industrial Organic Chemistry, Warsaw, Poland Study Code: BC-16/14-02 GLP - YES Unpublished	Y	Chemiroł
KCP 2.3.1/01	Frączak M.	2014	Clopyralid 300 SL (CHR/H/CPD) Determination of flash point and auto-ignition temperature of liquid Institute of Industrial Organic Chemistry, Warsaw, Poland Study Code: BC-16/14-01 GLP - YES Unpublished	Y	Chemiroł

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 2.3.3/01	Frączak M.	2014	Clopyralid 300 SL (CHR/H/CPD) Determination of flash point and auto-ignition temperature of liquid Institute of Industrial Organic Chemistry, Warsaw, Poland Study Code: BC-16/14-01 GLP - YES Unpublished	Y	Chemiroł
KCP 2.4.2/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.4.2/02	Al Amin I.	2015	Clopyralid 300 SL (CHR/H/CPD) Stage II: Determination of the physicochemical properties after the first year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.4.2/03	Al Amin I.	2016	Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł

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KCP 2.4.2/04	Al Amin I.	2017	Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł
KCP 2.4.2/05	Al Amin I.	2017	Annex No.1 to Final Raport Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.5.1/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.5.2/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 2.5.3/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.5.3/02	Al Amin I.	2017	Annex No.2 to Final Raport Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.6.1/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.7.1/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł

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KCP 2.7.4/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.7.5/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.7.5/02	Al Amin I.	2016	Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 2.7.5/03	Al Amin I.	2017	Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemirool
KCP 2.8.2/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemirool
KCP 2.8.2/02	Al Amin I.	2017	Annex No.2 to Final Raport Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemirool
KCP 2.8.4/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemirool

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 2.8.4/02	Al Amin I.	2015	Clopyralid 300 SL (CHR/H/CPD) Stage II: Determination of the physicochemical properties after the first year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.8.4/03	Al Amin I.	2016	Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł
KCP 2.8.4/04	Al Amin I.	2017	Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł
KCP 2.8.4/05	Al Amin I.	2017	Annex No.2 to Final Raport Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physicochemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 2.8.8.2/01	Al Amin I.	2014	Clopyralid 300 SL (CHR/H/CPD) Stage I: Determination of physico-chemical properties of initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.8.8.2/02	Al Amin I.	2015	Clopyralid 300 SL (CHR/H/CPD) Stage II: Determination of the physicochemical properties after the first year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/14 GLP - YES Unpublished	Y	Chemiroł
KCP 2.8.8.2/03	Al Amin I.	2016	Clopyralid 300 SL (CHR/H/CPD) Stage III: Determination of the physicochemical properties after the second year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł
KCP 2.8.8.2/04	Al Amin I.	2017	Clopyralid 300 SL (CHR/H/CPD) Stage IV: Determination of the physicochemical properties after the third year of storage Institute of Industrial Organic Chemistry, Warsaw, Poland Study code no. BF-13/17 GLP - YES Unpublished	Y	Chemiroł

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 2.9.1/01	Al Amin I.	2016	CHR/H/PCR + CHR/H/CPD Evaluation the physical and chemical compatibility Study code no. BF-74/16 GLP - YES	Y	Chemirool
KCP 2.9.1/01	Al Amin I.	2016	CHR/H/PCR + CHR/H/CPD + CHR/H/MTC Evaluation the physical and chemical compatibility Study code no. BF-75/16 GLP - YES	Y	Chemirool
KCP 2.9.2/01	Al Amin I.	2016	CHR/H/PCR + CHR/H/CPD Evaluation the physical and chemical compatibility Study code no. BF-74/16 GLP - YES	Y	Chemirool
KCP 2.9.2/02	Al Amin I.	2016	CHR/H/PCR + CHR/H/CPD + CHR/H/MTC Evaluation the physical and chemical compatibility Study code no. BF-75/16 GLP - YES	Y	Chemirool

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