

# 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: HCV08

Product name: Vivendi 300 SL, Auksendy 300 SL, Cliophar Super

Chemical active substance:

Clopyralid-ethanolamine, 395 g/l (300 g ae/l)

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(Renewal of Authorization under Art.43)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: December 2021

Revised version: April 2022

MS Finalisation date: July 2023 (initial Core Assessment)

March 2024 (final Core Assessment)

## Version history

When	What
December 2021	Article 43 submission for reregistration of HCV07 following Clopyralid Renewal of approval (Commission Implementing Regulation (EU) 2021/1191)
April 2022	Art 43: renewal of authorization revision and composition change from HCV07 to HCV08.  This update is submitted in order to demonstrate that the composition change consisting in the replacement of the antifoam in HCV07 to HCV08 doesn't impact physico-chemical properties of Clopyralid 300 SL comparing the results of the persistence foaming test conducted with HCV07 and HCV08 . Therefore, all other studies conducted with HCV07 support HCV08.
July 2023	Initial zRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b> . Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.
March 2024	Final report (Core Assessment updated following the commenting period)  No additional information or assessments after the commenting period.

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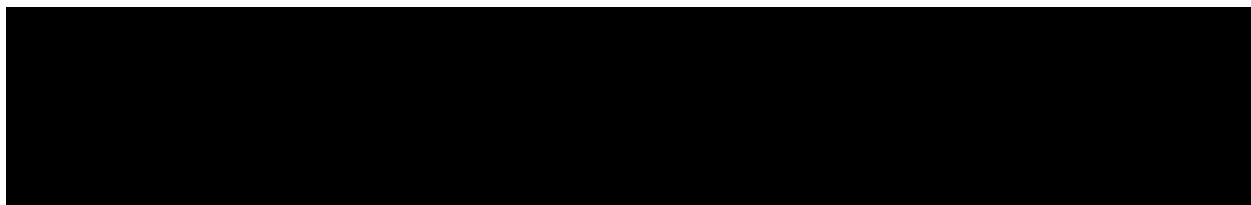
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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.

Noticed data gaps are: none.

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**



### **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**

End-Point	Clopyralid
Reference	Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021
Purity of active substance	950 g/kg minimum

There are no impurities of toxicological/ecotoxicological concern in clopyralid.

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

Trade name: Vivendi 300 SL, Auksendy 300 SL, Cliophar Super 300 SL

Company code number: HCV08

### **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 <sup>1</sup> (min – max)	Technical content <sup>2</sup> (g/L or g/kg)	Technical content <sup>3</sup> (%w/w)
Clopyralid (Clopyralid-monoethanolamine <sup>4</sup> )	300 g/L (395 g/L)	285 – 315 g/L (375 – 415 g/L)	315.8 g/L (416 g/L)	27.7 (36.5)

1. FAO limits for above 250 up to 500 g/L  $\pm$  5%
2. Based on the minimum purity of the active substance (950 g/kg)
3. Based on the nominal density of the formulation = 1.14 g/mL
4. a.e. factor for clopyralid-monoethanolamine = 0.759

**Table 1.4-2: Safeners and synergists**

There are no safeners or synergists in HCV08.

**Table 1.4-3: Relevant impurities**

There are no relevant impurities in HCV08.

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

**Table 1.4-4: Information on clopyralid**

Type	Name/Code Number	
ISO common name	Clopyralid	Variant: Clopyralid-monoethanolamine
CAS No.	1702-17-6	57754-85-5
EC No.	216-935-4	260-929-4
CIPAC No.	455	455.110

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

CONFIDENTIAL information is provided separately (Part C).

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

Type: Soluble concentrate

Code: SL

### 1.6 Function (KCP 1.6)

Herbicide

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

This update is submitted in order to demonstrate that the composition change consisting in the replacement of the antifoam in HCV07 to HCV08 doesn't impact physico-chemical properties of Clopyralid 300 SL comparing the results of the persistence foaming test conducted with HCV07 and HCV08. Therefore, all other studies conducted with HCV07 support HCV08.

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 a brown liquid. It is not explosive, has no oxidising properties. The product has a flash point of >76 °C. It has a self ignition temperature of greater than 400°C. In aqueous solution, it has a pH value around 5.3. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 2 weeks at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a SL formulation.

The intended concentration of use is 0.13% v/v to 1.2% v/v.

No application is being made for the authorisation of the combined use of the preparation with any other product. ~~However, the product is expected to be compatible (physically/chemically) in mixtures with other commercial products in agitated spray tanks.~~

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

Not relevant. No physical chemical hazards identified.

### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

Not relevant. No physical chemical hazards identified.

### **Compliance with FAO specifications:**

The product HCV08 complies with FAO specifications.

### **Formulation used for tests**

The composition of the products used in the physical/chemical properties tests is the same 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)	Visual	Clopyralid 300 SL (HCV07) Batch: 026060	Brown liquid	Y	Simons, J.P. (2000) 0006023.08.0001	Accepted.
Explosive properties (KCP 2.2.1)	N/A - statement		An assessment of the explosive properties of the test substance was carried out by analysing the chemical structures of the components of the formulation and comparing the bond groupings with those known to confer explosibility. The test substance does not contain components having any bond groupings known to confer explosibility.  Not explosive	N	Vanhoof, B. (2005) S050350-87130	Accepted.  Vivendi 300 is not explosive. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Oxidizing properties (KCP 2.2.2)	N/A - statement		An analysis of the chemical structures of the components of the substance shows that it will not possess oxidising properties and will not give rise to highly exothermic reactions when in contact with other substances, particularly flammable ones, in the manner in which recognised oxidizing substances do.  Non-oxidizing	N	Vanhoof, B. (2005) S050350-87130	Accepted.  Vivendi 300 has no oxidizing properties. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flash point (KCP 2.3.1)	EEC A9	Clopyralid 300 SL (HCV07) Batch: 016016	>76°C	Y	van Dijk, K. (2006) 0601043.08.0003	Accepted.  The formulation is not flammable.  The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																
Flammability (KCP 2.3.2)	-	-	Not applicable to SL formulations.	-	-	-																
Self-heating (KCP 2.3.3)		TSN400033, 394 g/L clopyralid-olamine	None below 400°C	Y	191214, Cowlyn, N., 2019	Accepted.  The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.																
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.2	Clopyralid 300 SL (HCV07) Batch: 026060	Neat pH: Before storage: 5.3 After 2 weeks at 54°C: 5.0  Neat pH: After 2 years at ambient in HDPE: 4.7  Determination of acidity/alkalinity is not applicable; pH of a 1% aqueous solution was not less than 4 or greater than 10	Y  Y	Simons, J.P. (2000) 0006023.08.0001  Simons, J.P. (2002) 0006023.08.0002	Accepted. The acidity or alkalinity was not determined because the pH of the test substance was between 4.0 and 10.0.  Accepted.																
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.2	Clopyralid 300 SL (HCV07) Batch: 026060	Before storage: pH = 6.0 After 2 weeks at 54°C: 5.6  After 2 years of ambient storage in HDPE: pH = 5.8	Y  Y	Simons, J.P. (2000) 0006023.08.0001  Simons, J.P. (2002) 0006023.08.0002	Accepted.  Accepted.																
Viscosity (KCP 2.5.1)	OECD 114	Clopyralid 300 SL (HCV07) Batch: 016016	At 20.0°C: mean viscosity = 3.093 mPa·s <table border="1"><tr><th colspan="2">Sample</th><th>temperature [°C]</th><th>Efflux time [sec.]</th><th>Kinematic viscosity [mm²/s]</th><th>Mean kinematic viscosity [mm²/s]</th></tr><tr><td rowspan="2">Clopyralid 300 g/l SL 016016</td><td>A</td><td>20.1-20.1</td><td>341</td><td>3.097</td><td rowspan="2">3.093</td></tr><tr><td>B</td><td>20.1-20.1</td><td>340</td><td>3.088</td></tr></table> At 40.0°C, mean viscosity = 1.753 mPa·s	Sample		temperature [°C]	Efflux time [sec.]	Kinematic viscosity [mm²/s]	Mean kinematic viscosity [mm²/s]	Clopyralid 300 g/l SL 016016	A	20.1-20.1	341	3.097	3.093	B	20.1-20.1	340	3.088	Y	van Dijk, K. (2006) 0601043.08.0003	Accepted.
Sample		temperature [°C]	Efflux time [sec.]	Kinematic viscosity [mm²/s]	Mean kinematic viscosity [mm²/s]																	
Clopyralid 300 g/l SL 016016	A	20.1-20.1	341	3.097	3.093																	
	B	20.1-20.1	340	3.088																		



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																
			<table><tr><td colspan="2">Sample</td><td>temperature [°C]</td><td>Efflux time [sec.]</td><td>Kinematic viscosity [mm²/s]</td><td>Mean kinematic viscosity [mm²/s]</td></tr><tr><td rowspan="2">Clopyralid 300 g/l SL 016016</td><td>A</td><td>39.9-39.9</td><td>193</td><td>1.753</td><td rowspan="2">1.753</td></tr><tr><td>B</td><td>39.9-40.0</td><td>193</td><td>1.753</td></tr></table>	Sample		temperature [°C]	Efflux time [sec.]	Kinematic viscosity [mm²/s]	Mean kinematic viscosity [mm²/s]	Clopyralid 300 g/l SL 016016	A	39.9-39.9	193	1.753	1.753	B	39.9-40.0	193	1.753			
Sample		temperature [°C]	Efflux time [sec.]	Kinematic viscosity [mm²/s]	Mean kinematic viscosity [mm²/s]																	
Clopyralid 300 g/l SL 016016	A	39.9-39.9	193	1.753	1.753																	
	B	39.9-40.0	193	1.753																		
Surface tension (KCP 2.5.2)	EEC A5	Clopyralid 300 SL (HCV07) Batch: 026060  Clopyralid 300 SL (HCV07) Batch: 016016	0.13% v/v in water: 20°C: 46 mN/m  3.43% v/v in water: 20°C: 34 mN/m  As concentrated formulation: 25°C: 26.4 mN/m  HCV07 is surface active.	Y  Y	Simons, J.P. (2000) 0006023.08.0001  van Dijk, K. (2006) 0601043.08.0003	Accepted.  The formulation is surface active.																
Relative density (KCP 2.6.1)	EEC A3	Clopyralid 300 SL (HCV07) Batch: 026060	1.1414 g/mL	Y	Simons, J.P. (2000) 0006023.08.0001	Accepted.																
Bulk density (KCP 2.6.2)	-	-	Not applicable to SL formulations.	-	-	-																
Storage Stability after 14 days at 54° C (KCP 2.7.1)		Clopyralid 300 SL (HCV07) Batch: 026060	Before storage: 293.5 g/L clopyralid After 2 wks at 54°C: 291.1 g/L clopyralid Considered stable for 14 days at 54°C  The content of clopyralid was determined in duplicate by a HPLC method based on a method obtained from Ministere des classes moyennes et de l'agriculture, Liege, Belgium. <table><tr><td>Parameters required for stability studies - Soluble</td><td>Initial</td><td>After 54°C</td></tr></table>	Parameters required for stability studies - Soluble	Initial	After 54°C	Y	Simons, J.P. (2000) 0006023.08.0001	Accepted. The product showed no significant physical changes after accelerated storage.  No significant changes were observed in the HDPE packaging and therefore it can be concluded that the test item was not corrosive to the container material.													
Parameters required for stability studies - Soluble	Initial	After 54°C																				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			concentrate (SL)					The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.
			Appearance	a homogenous liquid	a homogenous liquid			
			Description	brown	brown			
			pH (MT 75.2)	5.3	5			
			pH of a 1% dispersion (MT 75.2)	6	5.6			
			Dilution stability (CIPAC MT 41)	After dilution there wasn't any separated material notified.	After dilution after storage at 54°C there wasn't any separated material notified.			
			Packing detail: a Round translucent white, High Density Polyethylene HDPE, 1 litre container closed with induction heat seal and 45 mm plastic screw cap closure was used.	The test package was intact and no deformation was observed.	The test package was intact and no deformation was observed.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not applicable.			-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	See KCP 2.7.1			-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.2	Clopyralid 300 SL (HCV07) Batch: 026060	After storage at 0°C for 7 days no change in product characteristics was noted. The product is stable under cold storage conditions.			Y	Simons, J.P. (2000) 0006023.08.0001	Accepted.
Ambient temperature shelf life (KCP 2.7.5)		Clopyralid 300 SL (HCV07)	In HDPE: Before storage: 293.5 g/L After 2 years: 297.6 g/L			Y	Simons, J.P. (2002) 0006023.08.0002	Study accepted.  The HDPE container

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																					
		Batch: 026060	<div>See individual Annex points for the results of the physical properties tests.</div> <div>The content of clopyralid was determined in duplicate by a HPLC method based on a method obtained from Ministere des classes moyennes et de l'agriculture, Liege, Belgium.</div> <table><tr><td>Parameters required for stability studies - Soluble concentrate (SL)</td><td>Initial</td><td>After 2 years</td></tr><tr><td>Appearance</td><td>a homogenous liquid</td><td>a homogenous liquid</td></tr><tr><td>Description</td><td>brown</td><td>brown</td></tr><tr><td>pH (MT 75.2)</td><td>5.3</td><td>4.7</td></tr><tr><td>pH of a 1% dispersion (MT 75.2)</td><td>6</td><td>5.8</td></tr><tr><td>Dilution stability (CIPAC MT 41)</td><td>After dilution there wasn't any separated material notified.</td><td>After dilution there wasn't any separated material notified.</td></tr><tr><td>Packing detail: a Round translucent white, High Density Polyethylene HDPE, 1 litre container closed with induction heat seal and 45 mm plastic screw cap closure was used.</td><td>The test package was intact and no deformation was observed.</td><td>The test package was intact and no deformation was observed.</td></tr></table>	Parameters required for stability studies - Soluble concentrate (SL)	Initial	After 2 years	Appearance	a homogenous liquid	a homogenous liquid	Description	brown	brown	pH (MT 75.2)	5.3	4.7	pH of a 1% dispersion (MT 75.2)	6	5.8	Dilution stability (CIPAC MT 41)	After dilution there wasn't any separated material notified.	After dilution there wasn't any separated material notified.	Packing detail: a Round translucent white, High Density Polyethylene HDPE, 1 litre container closed with induction heat seal and 45 mm plastic screw cap closure was used.	The test package was intact and no deformation was observed.	The test package was intact and no deformation was observed.			showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product.  Period of validity: 2 years.
Parameters required for stability studies - Soluble concentrate (SL)	Initial	After 2 years																									
Appearance	a homogenous liquid	a homogenous liquid																									
Description	brown	brown																									
pH (MT 75.2)	5.3	4.7																									
pH of a 1% dispersion (MT 75.2)	6	5.8																									
Dilution stability (CIPAC MT 41)	After dilution there wasn't any separated material notified.	After dilution there wasn't any separated material notified.																									
Packing detail: a Round translucent white, High Density Polyethylene HDPE, 1 litre container closed with induction heat seal and 45 mm plastic screw cap closure was used.	The test package was intact and no deformation was observed.	The test package was intact and no deformation was observed.																									
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not applicable. The product was stable for at least 24 months at ambient temperature in HDPE.	-	-	-																					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Wettability (KCP 2.8.1)	-	-	Not applicable to SL formulations.	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	Clopyralid 300 SL (HCV07) Batch: 026060	3.45% dilution: 0 mL foam after 1 minute before storage and 0 mL foam after 1 minute after 2 weeks of storage at 54°C	Y	Simons, J.P. (2000) 0006023.08.0001	Accepted.
Persistence of foaming measurement (KCP 2.8.2)	CIPAC MT 47.2	Clopyralid 300 SL (HCV08) Batch: 21001649)	Dilution in 200 ml: 2 mL after 10 sec, 1 mL foam after 3 minute and 12 minutes. Test carried out with 6,89 g of test substance at temperature between 22-23°C.	N	Briffoz, A. (2022). Persistent test. Non GLP.	Accepted.
Suspensibility (KCP 2.8.3.1)	-	-	Not applicable to SL formulations.	-	-	-
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not applicable to SL formulations.	-	-	-
Dispersion stability (KCP 2.8.3.3)	-	-	Not applicable to SL formulations.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41	Clopyralid 300 SL (HCV07) Batch: 026060	Uniform solution without any separated material at 3.46% v/v in standard water, after 18 hours of standing at 30°C.  After 2 years storage in HDPE: Uniform solution without any separated material at 3.45% v/v in standard water, after 18 hours of standing at 30°C	Y  Y	Simons, J.P. (2000) 0006023.08.0001  Simons, J.P. (2002) 0006023.08.0002	Accepted.
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not applicable to SL formulations.	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not applicable to SL formulations.	-	-	-
Dust content (KCP 2.8.5.2.1)	-	-	Not applicable to SL formulations.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not applicable to SL formulations.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not applicable to SL formulations.	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not applicable to SL formulations.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not applicable to SL formulations.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not applicable to SL formulations.	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not applicable to SL formulations.	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not applicable to SL formulations.	-	-	-
Pourability (KCP 2.8.7.2)	-	-	Not applicable to SL formulations.	-	-	-
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not applicable to SL formulations.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Product is expected to be physically compatible with other commercial products in agitated spray tanks.	-	-	No application is being made for the authorisation of the combined use of the preparation with any other product.
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Product is expected to be chemically compatible with other commercial products in agitated spray tanks.	-	-	No application is being made for the authorisation of the combined use of the preparation with any other product.
Adhesion to seeds (KCP 2.10.1)	-	-	Not applicable; not a seed treatment	-	-	-
Distribution to seed	-	-	Not applicable; not a seed treatment	-	-	-

Annex point	Method used / deviations	Test mate- rial	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.10.2)						
Other/special studies (KCP 2.11)	-	-	Not applicable	-	-	-

### 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)

Comments of zRMS:	The accelerated stability data and ambient temperature storage stability data indicate a shelf life of at least 2 years when stored in HDPE containers. For aqueous based formulation type SL extrapolation between any plastic material types is acceptable. All packaging can be considered appropriate.
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**Table 4.1-1: Packaging information for PET bottles**

Type	Description
Material:	PET
Shape/size:	Bottles/Jerrican for 0.25, 0.5, 1, 2, 3 and 5 L
Opening:	28, 45, 63 mm inner diameter
Closure:	Screw cap with additional induction sealing disk
Seal:	Induction, bore, compression or vented
Manner of construction	Stretch blow moulded
UN/ADR	Compliant

**Table 4.1-2: Packaging information for HDPE bottles**

Type	Description
Material:	HDPE
Shape/size:	Bottles/Jerrican for 0.25, 0.3, 0.5, 0.6, 1 and 5 L
Opening:	28, 45, 50, 60, 61 and 63 mm inner diameter
Closure:	Screw cap with additional induction sealing disk
Seal:	Induction, compression or vented
Manner of construction	Extruded
UN/ADR	Compliant

No alteration of the containers and no change in appearance was noticed. No significant loss of weight was observed in HDPE containers.

### 4.2 Procedures for Cleaning Application Equipment

Comments of zRMS:	Accepted. Triple rinse is recommended.
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#### **Tank Clean (study 191711)**

Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, bottom and nozzles two to three times with clean water until the foam and all traces of product have been removed.

Clopyralid is very soluble and exhibits no propensity to adhere to materials used in the construction of spray machinery. In over 40 years of commercial use, no difficulty in cleaning application equipment has been reported. Once diluted in the spray tank, the spray solution created by using GF-1966 (720 g/kg clopyralid, SL) is identical to that created by other “straight” clopyralid formulations.

Consider the following calculation:

Worse case EU single application is 120 g ae/ha in 100 L/ha of water.

For example, using a 1000L capacity sprayer. I.e. the sprayer would contain enough spray solution to treat 10 ha and would therefore have been loaded with 1200 gae of clopyralid.

After spraying is complete worse case 10% (more likely 1% for a well-designed sprayer) of the spray solution would stay in the tank containing 120 gae of clopyralid.

Fill the tank with water and agitate. Spray out, leaving 10% of the spray solution containing 12 gae of clopyralid.

Fill the tank with water and agitate (i.e. fill for the second time). Spray out, leaving 10% of the spray solution containing 1.2 gae of clopyralid.

The next time the sprayer is used it would be filled with 1000L of water and the 1.2 gae of clopyralid would be sprayed across 10ha i.e. 0.12 gae/ha might be applied as worse case.

The most sensitive species in seedling emergence tests was soybean (*Glycine max*) with an ER<sub>50</sub> value of 25.64 g clopyralid/ha. The most sensitive species in the vegetative vigour test was Tomato (*Lycopersicon esculentum*) with an ER<sub>50</sub> value of 21.74 g clopyralid/ha.

This calculation demonstrates that even using the most pessimistic assumptions, the amount of clopyralid that would remain in the application equipment after cleaning would be much too low to cause damage to even the most sensitive species.



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

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1, KCP 2.4.1, KCP 2.4.2, KCP 2.5.2, KCP 2.6.1, KCP 2.7.1, KCP 2.7.4, KCP 2.8.2, KCP 2.8.4	Simons, J.P.	2000	Determination of the physical and chemical properties of Clopyralid 300 g/l SL Brabant Chemie Report No. 0006023.08.001 GLP Unpublished	N	UPL
KCP 2.2.1, KCP 2.2.2	Vanhoof, B.	2005	Statement on the Flash point and Explosive and Oxidizing properties of CLOPYRALID 300 G/L SL AgriChem B.V., Oosterhout (NL) Report no. S050350-87130 Non-GLP Not published	N	UPL
KCP <del>2.3.2</del> <u>2.3.3</u>	Cowlyn, N.	2019	Determination of Oxidising Properties, Auto-Ignition Temperature and Surface Tension of EF-243 191214 Covance CRS Limited GLP Unpublished	N	Corteva Agriscience
KCP 2.3.1, KCP 2.5.1	van Dijck, K.	2006	Determination of the density at 40°C, viscosity, the surface tension of the neat formulation at 25°C and flash-point of Clopyralid 300 g/l SL Brabant Chemie Report No. 0601043.08.003 GLP Unpublished	N	UPL
KCP 2.4.2, KCP 2.5.2, KCP 2.7.5, KCP 2.8.4	Simons, J.P.	2002	Determination of the physical and chemical properties of Clopyralid 300 g/l SL after 2 years storage at room temperature Brabant Chemie Report No. 0006023.08.002 GLP Unpublished	N	UPL
KCP 2.8.2	Briffoz, A.	2022	Persistence of foaming measurement test. Clopyralid 300 SL (HCV08) Batch: 21001649.	N	UPL

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
			CIPAC MT 47.2 Non GLP Unpublished		
KCP 4.2	Huby, JP.	2019	GF-1966 Tank Clean Out Study Following EPPO 1/292 guidance 191711 Corteva Agriscience nonGLP Unpublished	N	Corteva Agriscience
<del>KCA 2.5</del>	<del>Whiting, S.</del>	<del>2018</del>	<del>Determination of Water Solubility (Shake Flask Method) NAFST 180074 EAG, Inc. GLP Unpublished</del>	<del>N</del>	<del>Corteva Agriscience</del>
<del>KCA 2.6</del>	<del>Tunink, A.</del>	<del>2018</del>	<del>Determination of Organic Solvent Solubility (Shake Flask Method) NAFST 180071 EAG, Inc. GLP Unpublished</del>	<del>N</del>	<del>Corteva Agriscience</del>
<del>KCA 2.7</del>	<del>Whiting, S.</del>	<del>2018</del>	<del>Determination of n-Octanol/Water Partition Coefficient (Shake Flask Method) NAFST 180073 EAG, Inc. GLP Unpublished</del>	<del>N</del>	<del>Corteva Agriscience</del>

**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**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

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

Summaries for Clopyralid solubility in water, solubility in organic solvents and n-Octanol/Water partition coefficient.

### A 2.1 Clopyralid

#### A 2.1.1 Solubility in water (KCA 2.5)

The solubility of clopyralid (pure) has been determined in in unbuffered water, pH 4 buffer, pH 7 buffer and pH 9 buffer. The water solubility was determined using the shake flask method. The test substance solutions were analysed by a high-performance liquid chromatography system with ultraviolet detection (HPLC-UV).

The solubility of clopyralid in unbuffered water was found to be 8.41 g/L at 20°C, solubility of clopyralid in pH 4 buffer was found to be 354 g/L at 20°C, solubility of clopyralid in pH 7 buffer was found to be 345 g/L at 20°C, and solubility of clopyralid in pH 9 buffer was found to be 336 g/L at 20°C. (Whiting, S (2018) NAFST-180074)

### A 2.2 Clopyralid

#### A 2.2.1 Solubility in organic solvents (KCA 2.6)

The solubility of clopyralid has been determined in acetone, methanol, ethyl acetate, n-octanol, 1,2-dichloroethane, p-xylene and n-heptane. The solubility in organic solvents was determined using the shake flask method. The test substance solutions were analysed by a high-performance liquid chromatography system with ultraviolet detection (HPLC-UV).

The solubility of clopyralid in organic solvents are represented in the table below. (Tunink, A (2018) NAFST-180071)

Solvent	Determined Solubility (mg/mL)	Converted Solubility (g/kg)
Acetone	-	>250
Methanol	-	>250
Ethyl Acetate	88.0	97.5
n-Octanol	98.7	119
1,2-dichloroethane	20.0	15.9
p-Xylene	5.01	5.79
n-Heptane	0.0807	0.118

### A 2.3 Clopyralid

#### A 2.3.1 n-Octanol/Water partition coefficient (KCA 2.7)

The n-Octanol/Water partition coefficient of clopyralid has been determined in reagent water, pH 4, pH 7 and pH 9. The n-octanol/water partition coefficient was determined using the shake flask method. The test substance solutions were analysed by a high-performance liquid chromatography system with ultraviolet detection (HPLC-UV).

The overall mean n-octanol/water partition coefficients and corresponding mean log  $P_{ow}$  values for clopyralid in reagent water and at pH 4, 7, and 9 at 20°C are provided in the following table (Whiting, S (2018) NAFST-180073)

Aqueous Phase	Overall Mean Octanol/Water Partition Coefficient ( $P_{ow}$ )	Mean log $P_{ow}$ $\pm$ Absolute Std. Dev.
Reagent Water	2.48	$0.395 \pm 0.045$
pH 4	0.0929	$-1.03 \pm 0.06$
pH 7	0.00265	$-2.58 \pm 0.04$
pH 9	0.00186	$-2.73 \pm 0.01$