

# REGISTRATION REPORT

## **Part B**

### **Section 0**

Product Background, Regulatory Context and  
GAP information

Product code: HCV08

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

Chemical active substance:

Clopyralid-olamine, 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: 22/12/2021

MS Finalisation date: October 2023 (initial Core Assessment)

April 2024 (final Core Assessment), updated January 2025

## 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.  The proposed change in the composition was accepted, the studies presented for the formulations code HCV07 are still supporting the registration of the plant protection product. To support the new formulation (HV08) after the composition change, a new persistence of foaming study has been performed. Additional studies are not required.
October 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.
April 2024	Final report (Core Assessment updated following the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments received from the Applicant are <b>highlighted in yellow</b> . Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.
January 2025	Honey MRL update  Additional information/assessments included by the zRMS in the report after the MRL for honey change in Commission Regulation (EU) 2024/2612 are <b>highlighted in yellow</b> . Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.

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## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

This application is made to fulfil the requirements of Article 43 of Regulation (EC) No 1107/2009 for the authorization of the product HCV07. This is a renewal of product submission in the Central zone.

This document describes the product background, regulatory context and GAP information required for the registration of HCV07 containing 395 g/L (300 g ae/L) Clopyralid-olamine.

#### 0.1.1 Reason for application

This draft Registration Report (dRR) supports an application for the Article 43 product resubmission in the Central zone, with Poland as the Rapporteur Member State. The product (development code HCV07) is a soluble concentrate (SL) containing Clopyralid – olamine (395 g/L (300 g ae/L)) as the active substance. The product is intended to be used as a herbicide.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 545/2011 as appropriate for plant protection product registration– see SANTE/11509/2013 – rev 5.2 guidance document on interpretation of the transitional measures for the data requirements for chemical active substances and plant protection products according the Regulation (EU) No. 283/2013 and 284/2013. The dossier is supported with a full package as outlined in the requirements. Corteva Agriscience is the data owner for active substance contained in HCV07, for which UPL have access *via* a letter of access. The table below provides new information submitted in comparison with the previous review for HCV07 in Central Zone.

**Table 0.1-1: New information in comparison with the previous review**

Section	New information in this submission vs previous review
Section 1,2 and 4	Full physchem data package
Section 3 (Efficacy)	New efficacy dossier
Section 5 (Methods)	Methods for additional residue and ecotoxicological studies in the dossier
Section 6 (Toxicology)	-
Section 7 (Residues and metabolism)	Metabolism in wheat Metabolism OSR Residue trials in supported crops Field rotational crop Storage stability for some of supported crops Honey study
Section 8 (Environmental Fate)	E-fate modeling based on new agreed endpoints
Section 9 (Ecotox)	Acute oral tox. Birds Aquatic toxicity studies Bumble bee (a.s.) Effects on soil non target organisms Effects on non target plants (seedling emergence and vegetative vigour)
Section 10 (Non-relevance of metabolites)	-
Part C (Confidential information)	-

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. Full data package was submitted by Corteva Agriscience.

## 0.1.2 Details of zRMS(s) and concerned MS

Article 43 submission in Central zone with Poland as zRMS, details provided in Table 0.1-1.

**Table 0.1-2: Overview of zRMS and cMS**

	zRMS, product name and authorization no.	Concerned MS, MS' product name and authorization number
<b>Central zone</b>	<u>zRMS – Poland</u> <u>Products:</u> Vivendi 300 SL, Auksendy 300 SL, Cliophar Super 300 SL Authorization numbers – R-14/2015, R-64/2017 and R-20/2020	<u>N/A</u>

## 0.1.3 Regulatory history of the active(s)

**Table 0.1-3: Summary of regulatory history of CAS No: 1702-17-6**

<b>Status</b>	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021
RMS	Finland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.10.2021
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	NA
Date of final Commission (re-registration) deadline (Step 2)	NA
Current expiration of approval	30.09.2036
Low risk substance or Candidate for Substitution?	No

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the specification of the technical material as commercially manufactured;
- the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment;
- possible presence of clopyralid residues in rotational crops;
- the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops;
- the protection of groundwater under vulnerable conditions.

Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit this information within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

The SANTE report for clopyralid (SANTE/10206/2021 Rev 1) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 03/08/2018 (EFSA Journal 2018;16(8):5389).

**Table 0.1-4: Information on minimum purity of clopyralid**

EU agreed minimum purity from Inclusion Directive or Implementing regulation
$\geq 950$ g/kg

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA 2018	Endpoint used*
<i>Bombus terrestris</i>	Not applicable	Oral LD <sub>50</sub> = >203 µg a.s./bee Contact LD <sub>50</sub> = >200 µg a.s./bee
Stability of Crop Residues	Clopyralid (free and conjugated) is stable for at least 17 months in high water commodities, 24 months in high oil commodities, 13 months in high starch commodities and 10 months in high acid commodities when stored under frozen ( $\leq -18^{\circ}\text{C}$ ) conditions in the EFSA conclusion 2018a.	Clopyralid (free and conjugated) is stable across the five commodity categories and therefore is stable in all crop commodities up to 13 months when stored under frozen ( $\leq -18^{\circ}\text{C}$ ) conditions.
Dermal absorption	Concentrate: 25 % Spray dilution: 75 % Default dermal absorption values according to Guidance on Dermal Absorption (EFSA PPR Panel, 2012)	Concentrate: 10% EFSA default value for concentrated SL formulation (active substance concentration > 50 g/L) Spray dilution: 50% EFSA default value for dilute SL formulation (active substance concentration $\leq 50$ g/L)

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

### 0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Product code	Product names	MS	Authorization No.	Date of initial registration	Date of the last re-registration
HCV07	Vivendi 300 SL	Poland	R-14/2015	29.01.2015	NA
HCV07	Auksendy 300 SL	Poland	R-64/2017	12.04.2017	NA
HCV07	Cliophar Super 300 SL	Poland	R-20/2020	14.02.2020	NA

### 0.2 zRMS conclusion

For the overview of accepted uses of the product HCV08 see the Complete GAP table in Appendix 1 of this document. For detailed information see the GAP tables in the individual relevant sections.  
Additional minor crops, not existing in the current product labels such as: fodder beet, red beet, turnip, swede, spring oilseed rape, mustard, linseed are proposed to be authorised on the grounds of art. 51 of Regulation (EC) No 1107/2009.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

See column 15 of the GAP table presented in Appendix 1 of this document.


~~An exceedance of the current MRLs of for clopyralid as laid down in Reg. (EU) 396/2005 for proposed crops is not expected. However, an exceedance of the current MRL of 0.05 mg/kg for clopyralid in honey as laid down in Reg. (EU) 396/2005 may be expected. Until the new MRL has been set for honey, use on oilseed rape, mustard and linseed cannot be authorized.~~

The current MRL for clopyralid in honey has been changed and now is 0.15 mg/kg (Commission Regulation (EU) 2024/2612), and according to the provided study on magnitudes of residues in honey (UPL has access to this data *via* a letter of access), the MRL is not potentially exceeded. The uses on melliferous target crops (oilseed rape, mustard and linseed) can be authorized.

Appendix 1 ALL intended uses

GAP rev. 4 3 2 1, date: January 2025 April 2024 October 2023  
December 2021

PPP (product name/code):  
Active substance 1:  
Safener:  
Synergist:  
Applicant:  
Zone(s):  
Verified by MS:  
Field of use:

HCV07 / Vivendi 300 SL, Auksendy 300 SL, Cliophar Super  
Clopyralid-olamine  
NA  
NA  
UPL  
Central Zone  
yes   
herbicide

Formulation type:  
Conc. of as 1:  
Conc. of safener:  
Conc. of synergist:  
Professional use:  
Non professional use:

SL  
395 g a.s./L (300 g ae/L)  
NA  
NA  
☒  
☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (i)	zRMS Conclusion							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD, BRSRR, BRSNA EU MRL Code: 0213010, 0900010, 0213010  Raw Human consumption Processed goods Cattle consumption	F	Broad- leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar  Tractor mounted boom	BBCH 12- 19 39 (until July 1st)	a) 1 b) 1	NA	a) 0,3 to 0,4 b) 03 to 0,4	a) AS1: 118,578 to 158,104 (as/ha), 90 to 120 (ae/ha)  b) AS1: 118,578 to 158,104 (as/ha), 90 to 120 (ae/ha)	150- 300  100- 400 200- 300	42 days  F	One application every two years. Maximum total dose rate must not exceed 120 g ae/ha per crop; maximum individual dose: 120 g ae/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	A	A	A	A	R  Biennial application  (FOCUS PEARL 4.4.4)	A	A	A BEAVA  N  BEAVC, BEAVD, BRSRR, BRSNA (possible registration on the grounds of article 51)



2	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD, <b>BRSSRR</b> , <b>BRSSNA</b> EU MRL Code: 0213010, 0900010, 0213010  Raw Human consumption Processed goods Cattle consumption	F	Broad- leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar  Tractor mounted boom, split application	BBCH 12- 15 First application at BBCH 12-15. Second application at BBCH 12-15.	a) 2 b) 2	7 day interval	a) 0,2 b) 0,4	a) AS1: 79,052 (as/ha), 60 (ae/ha)  b) AS1: 158,104 (as/ha), 120 (ae/ha)	<del>100-</del> <del>400</del> <b>200-</b> <b>300</b>	<del>42-days</del> <b>F</b>	Only every <del>two</del> <b>three</b> years. Split application: First application at 60 gae/ha (0,2L/ha) at BBCH 12-15 followed 7-days later by a second application at BBCH 12- 15 at 60 gae/ha (0,2 L/ha). Maximum total dose rate must not exceed 120 g ae/ha per crop; maximum individual dose: 120 g ae/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	A	A	A	A	R  Biennial application  (FOCUS PEARL 4.4.4)	A	A	N  (possible registration on the grounds of article 51 for BEAVC, BEAVD, BRSSRR, BRSSNA)
3	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVD, BEAVA, <b>BRSSRR</b> , <b>BRSSNA</b> EU MRL Code: 0213010, 0213010, 0900010,  Raw Human consumption Processed goods Cattle consumption	F	Broad- leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar  Tractor mounted boom, split application	BBCH 12- 15 First application at BBCH 12-15. Second application at BBCH 12-15.	a) 2 b) 2	7 day interval	a) 0,175 b) 0,35	a) AS1: 69,17 (as/ha), 52,5 (ae/ha)  b) AS1: 138,341 (as/ha), 105 (ae/ha)	<del>100-</del> <del>400</del> <b>200-</b> <b>300</b>	<del>42-days</del> <b>F</b>	Only every <del>two</del> <b>three</b> years. Split application: First application at 52,5 gae/ha (0,175L/ha) at BBCH 12-15 followed 7-days later by a second application at BBCH 12- 15 at 52,5 gae clopyralid/ha (0,175 L/ha). Maximum total dose rate must not exceed 105 g ae/ha per crop; maximum individual dose: 105 g ae/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	A	A	A	A	R  Biennial application  (FOCUS PEARL 4.4.4))	A	A	N  (possible registration on the grounds of article 51 for BEAVC, BEAVD, BRSSRR, BRSSNA)
4	Poland	Fodder beet, Sugar beet, Red Beet,	F	Broad- leaved weeds	Broadcast, Foliar	BBCH 15- 31	a) 2 b) 2	10-day interval	a) 0,175 b) 0,35	a) AS1: 69,17 (as/ha),	<del>100-</del> <del>400</del> <b>200-</b>	<del>42-days</del> <b>F</b>	Every two years. Split application: first application at 52,5 gae/ha (0,175L/ha) at	A	A	A	A	R  Biennial	A	A	N  (possible

		Turnip, Swede EPPO Code: BEAVC, BEAVD, BEAVA, BRSRR, BRSNA EU MRL Code: 0213010, 0213010, 0900010,  Raw Human consumption Processed goods Cattle consumption		(BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Tractor mounted boom, split application	First application at BBCH 15. Second application at BBCH 31.				52,5 (ae/ha)  b) AS1: 138,341 (as/ha), 105 (ae/ha)	300		BBCH 15 followed 10 days later by a second application (at BBCH 31) at 52,5 gae /ha (0,175 L/ha). Maximum total dose rate must not exceed 105 g ae/ha per crop; maximum individual dose: 105 g ae/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.					application  (FOCUS PEARL 4.4.4)			registration on the grounds of article 51 for BEAVC, BEAVD, BRSRR, BRSNA)
5	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD, BRSRR, BRSNA EU MRL Code: 0213010, 0900010, 0213010  Raw Human consumption Processed goods Cattle consumption	F	Broad- leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar  Tractor mounted boom, split application	BBCH 15- 31  First application at BBCH 15. Second application at BBCH 31.	a) 2 b) 2	10-day interval	a) 0,2 b) 0,4	a) AS1: 79,05 (as/ha), 60 (ae/ha)  b) AS1: 158,1 (as/ha), 120(ae/ha)	100- 400 200- 300	42-days F	Every two years. Split application: first application at 60 gae/ha (0,2 L/ha) at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 60 gae/ha (0,2 L/ha). Maximum total dose rate must not exceed 120 g ae/ha per crop; maximum individual dose: 120 g ae/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	A	A	A	A	R  Biennial application  (FOCUS PEARL 4.4.4)	A	A	N  (possible registration on the grounds of article 51 for BEAVC, BEAVD, BRSRR, BRSNA)
6	Poland	Winter Oilseed rape, Spring Oilseed rape, Mustard, Linseed EPPO Code: BRSNW	F	Broad- leaved weeds (BBBBB) (including but not only Cirsium arvense,	Broadcast, Foliar  Tractor mounted boom	BBCH 30- 51	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (g as/ha), 120 (g ae/ha)  b) AS1:	100- 400 200- 300	Not applicable*	For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is	A	A	A	NA  Current MRL exceeded in-honey	A	A	A	A  BRSNW  Dose rate range 0,3-0,4 L/ha recommended according to the

		BRSNS, BRSJU, SINAL, LIUUT EU MRL Code: 0401060  Raw Human consumption Processed goods Cattle consumption		Centaurea cyanus, Matricaria spp)						158,104 (g as/ha), 120 (g ae/ha)			recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.								current product label.
																				N  BRSNS, BRSJU, SINAL, LIUUT (possible registration on the grounds of art. 51)	
7	Poland	Onion from Seeds EPPO Code: ALLCE EU MRL Code: 0220020  Raw Human consumption Processed goods	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast Foliar  Tractor mounted boom	BBCH 11-16	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (as/ha), 120 (ae/ha)  b) AS1: 158,104 (as/ha), 120 (ae/ha)	<del>100-400</del> 200-300	42-days	For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	A	A	A	A	R  Biennial application  (FOCUS PEARL 4.4.4)	A	A	A  Dose rate range 0,3-0,4 L/ha recommended according to the current product label

- Remarks table heading:**
- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
- (c) g/kg or g/l
- (d) Select relevant
- (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
- (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions
			15	Overall conclusions - explanation for the column 15 is below *

\* Explanation for column 15 “Overall conclusions”

A	Acceptable
	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible