FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: CHR/H/FDF 574 SC

Product name(s): Cezaro 574 SC/ Huron 574 SC

Chemical active substance(s):

Florasulam, 12 g/L
Diflufenican, 250 g/L

Flufenacet, 312 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: November 2020

MS Finalisation date: 21/11/2022

Version history

When	What
March 2022	Dossier sent for evaluation
September 2022	zRMS evaluation of dRR
November 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for authorization of CHR/H/FDF 574 SC (Cezaro 574 SC, Huron 574 SC) containing florasulam, diflufenican and flufenacet in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part A and C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to CHR/H/FDF 574 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/H/FDF 574 SC have been made using endpoints agreed in the EU review of florasulam, diflufenican and flufenacet.

This document describes the specific conditions of use and labelling required for the registration of (Cezaro 574 SC, Huron 574 SC product code CHR/H/FDF 574 SC.

0.1.1 Reason for application

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

In addition to the submission of studies as listed in section(s) B1-B10, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	Poland: CHR/H/FDF 574 SC Cezaro 574 SC/Huron 574 SC	

0.1.3 Regulatory history of the active(s)

0.1.3.1 Florasulam

Table 0.1-2: Summary of regulatory history of CAS No: 145701-23-1

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) 2015/1397 of 14 August 2015
RMS	PL
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2016
Date of first Commission (re-registration) deadline (Step 1) or date of	31/12/2030

Status	
deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	31/12/2030
Current expiration of approval	21/12/2030
Low risk substance or Candidate for Substitution?	LRS

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 risk to aquatic organisms and non-target terrestrial plants

The SANCO report for florasulam (SANTE/10542/2015 Rev 1 14/07/2015) 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 31.05.2015.

Table 0.1-3: Information on minimum purity of active substance

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
970 g/kg	For the purity of active substance, please refer to PART C- confidantial information Equivalence report available: Y (available on CIRCA) RMS: UK (COP 2015/00208)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.3.2 Diflufenican

Table 0.1-4: Summary of regulatory history of CAS No: 83164-33-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2008/66/EC of 30 June 2008
RMS	CZ
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/12/2022
Date of final Commission (re-registration) deadline (Step 2)	31/12/2022
Current expiration of approval	31/12/2022
Low risk substance or Candidate for Substitution?	

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:

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- the protection of aquatic organisms. Risk mitigation measures such as buffer zones should be applied, where appropriate.
- the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones should be applied, where appropriate.
-

The SANCO report for diflufenican (SANCO/3782/08 – rev. 1 14 March 2008) 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 31.08.2009

Table 0.1-5: **Information on minimum purity of diflufenican**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
970 g/kg	~~For the purity of active substance, please refer to PART C- confidantial information~~ Source 1 – 975 g/kg Source 2 – 985 g/kg Source 3 – 980 g/kg Source 4 – 975 g/kg

0.1.3.1 Flufenacet

Table 0.1-6: Summary of regulatory history of CAS No: 142459-58-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2003/84/EC of 25 September 2003
RMS	PL
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2004
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/10/2020
Date of final Commission (re-registration) deadline (Step 2)	31/10/2020
Current expiration of approval	~~31/10/2020~~ 31/10/2022
Low risk substance or Candidate for Substitution?	CfS

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:

- should pay particular attention to the protection of algae and aquatic plants.
- should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.
- should pay particular attention to the protection of operators.

Risk mitigation measures must be applied, where appropriate.

The SANCO report for Flufenacet 7469/VI/98-Final 3 July 2003 is considered to provide the relevant information on the evaluation or a reference to where such information can be found. There is no EFSA peer review at the moment of application

Table 0.1-7: Information on minimum purity of Flufenacet

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
950 g/kg	~~For the purity of active substance, please refer to PART C- confidantial information~~ Equivalence report available: Y (available on CIRCA) RMS:UK (CRD) Source 1 – 980 g/kg Source 2 – 980 g/kg Source 3 – 985 g/kg Source 4 – 975 g/kg

0.1.4 Regulatory history of the product

Not authorized yet.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
The two-year study is ongoing. It has to be provided for evaluation in Poland when available and can be done in post registration.
Based on physicochemical properties the PPP is not classified.

Section 3. Efficacy
The evaluation of the application of Huron 574 SC/Cezaro 574 SC resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical Methods
The analytical methods are accepted.

Section 6. Mammalian Toxicology
Taking into account the composition of the formulation the CHR/H/FDF 574 SC requires the classification as Skin Sens, 1 H317, Acute Tox. 4 H302 and STOT RE 2 H373.
There is no unacceptable risk to operator, worker, bystander and resident health if the product is used in accordance to the intended uses listed in the GAP table.
Risk mitigation:
Operator – clothing with long sleeves and trousers leg (M/L&A) and protective gloves against chemical (M/L)
Worker – work wear (arms, body and legs covered)
Residents/Bystanders – 5 m unsprayed buffer zones

Section 7. Metabolism and Residues
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

Section 8. Environmental Fate
In accordance with proposed pattern use, an exposure assessment for the formulation CHR/H/FDF 574 SC was submitted.

Section 9. Ecotoxicology
In accordance with proposed pattern use, risk assessment to non-target organisms for the formula-tion of CHR/H/FDF 574 SC/Cezaro 574 SC, Huron 574 SC was sufficient.
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of

CHR/H/FDF 574 SC/Cezaro 574 SC, Huron 574 SC as herbicide in winter cereals poses an ac-ceptable risk to non-target organisms in application rate 0.4 L/ha
Particular precautions to reduce the environmental concentrations resulting from CHR/H/FDF 574 SC/Cezaro 574 SC, Huron 574 SC applications are required for:
- aquatic organisms
- non-target terrestrial plants

Section 10. Assessment of the relevance of metabolites in groundwater
The PECgw values for relevant metabolites of active substances were corrected, if relevant, in accordance with PECgw values presented in dRR Section 8.
Florasulam. Based on PECgw assessment all relevant metabolites with concentration higher than trigger value of 0.1 µg/L were considered.
Flufenacet. The only metabolite FOE-sulfonic acid has to be considered. The PECgw value for this metabolite was above the trigger value of 10 µg/L for winter cereals in Jokioinen scenario and was not taken into account as this scenario is not relevant for Central Zone.
Diflufenican. The PECgw values for metabolites of active substance were below the trigger value of 0.1 µg/L.
ASTCA, TSA and 5-OH Florasulam
Genotoxicity studies were evaluated as part of the EU review process for florasulam. Results of these studies included in the EFSA Conclusions (EFSA Journal 2015;13(1): 3984). The metabolites did not demonstrate any genotoxic potential in an Ames test, a gen mutation assay *in vitro* with mammalian cells (CHO/HGPRT) and chromosomal aberration assay *in vitro*. Florasulam is not classified as acutely or chronically toxic or very toxic and is also not classified for reproductive toxicity and carcinogenicity.
ASTCA, TSA and 5-OH Florasulam are not considered to be toxicologically relevant.
FOE-sulfonic acid
The metabolite did not demonstrate any genotoxic potential in an Ames test, a gene mutation assay *in vitro* with mammalian cells and *in vitro* micronucleus assay.
The metabolite was exceed 0.75 µg/L in groundwater modelled scenario. Therefore, a refined exposure and risk assessment according to Step 5 was required. The estimated exposure for children and infants exceed the allocation factor of 20% based on the WHO Guidelines for drinking water. Therefore, exposure from other routes was assessed. Total exposure did not exceed the ADI.

Uses to be considered safe on the basis of EU methodology:
Use No 1.

Uses to be considered non-safe on the basis of EU methodology:
none

Appendix 1 ALL intended uses

GAP rev. , date: 2019-10-01

PPP product name:		Formulation type:	SC [a, b]
product code:	CHR/H/FDF		
Active substance 1:	flufenacet	Conc. of as 1:	312 g/l [c]
Active substance 2:	diflufenican	Conc. of as 2:	250 g/l [c]
Active substance 3:	florasulam	Conc. of as 3:	12 g/l (c)
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	PUH Chemirol Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐

Verified by MS: ~~no~~ yes

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	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 [f]	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			

Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI), Winter barley (HORVW), Winter rye (SECCW)	F	*Apera spica-venti* and dicotyledonous weeds	Spray, medium sprayer	autumn BBCH 11-25	a)1 b)1	n/a	a) 0.4 l/ha b) 0.4 l/ha	a) 0.2296 kg a.s./ha (0.1248 FLU + 0.1 D + 0.0048 FLO) b) 0.2296 kg a.s./ha (0.1248 FLU + 0.1 D + 0.0048 FLO)	200-~~400~~ 300	n/a		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
2														
3														
Minor uses according to Article 51 (zonal uses)														
4														
5														
Minor uses according to Article 51 (interzonal uses)														
6														
7														

Remarks table heading:

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

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

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3