FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: CHR/H/CFF 250 EC

Product name(s): Hapi 250 EC/ Turango 250 EC

Chemical active substance(s):

Clopyralid, 120 g/L

Fluroxypyr-acid, 120 g/L (as fluroxypyr-meptyl, 172.9 g/L)

Florasulam, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: March 2023

MS Finalisation date: September 2024; November 2024

Version history

When	What
09.2024	ZRMs evaluated dRR submitted by Applicant.
11.2024	The final Registration Report

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0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for authorization of CHR/H/CFF 250 EC (Hapi 250 EC, Turango 250 EC) containing clopyralid, fluroxypyr and florasulam 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/CFF 250 EC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/H/CFF 250 EC have been made using endpoints agreed in the EU review of clopyralid, fluroxypyr and florasulam

This document describes the specific conditions of use and labelling required for the registration of (Cevino Trio 599.5 SC, Trivino 599.5 SC), product code CHR/H/PENDIF 599.5 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/CFF 250 EC Hapi 250 EC/Turango 250 EC	

0.1.3 Regulatory history of the active(s)

0.1.3.1 Clopyralid

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:

Table 0.1-2: Summary of regulatory history of CAS No: 1702-17-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION IMPLEMENTING REGULATION (EU) 2021/566 of 30 March 2021
RMS	FI
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)	30.09.2036
Date of final Commission (re-registration) deadline (Step 2)	30.09.2036
Current expiration of approval	30.09.2036
Low risk substance or Candidate for Substitution?	N/A

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.

The SANCO report for clopyralid (SANTE/10206/2021 Rev 1-20 May 2021) 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.

Table 0.1-3: Information on minimum purity of clopyralid

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: ~~please refer to LoA~~ Yes RMS: please refer to LoA

* 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 Fluroxypyr meptyl

Table 0.1-4: Summary of regulatory history of CAS No: 69377-81-7

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 736/2011 of 26 July 2011
RMS	SE
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	-
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/12/2024
Date of final Commission (re-registration) deadline (Step 2)	31/12/2024
Current expiration of approval	31/12/2024
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 potential contamination of groundwater by metabolite fluroxypyr pyridinol, when the active substance is applied in regions with alkaline or vulnerable soil and/or with vulnerable climatic conditions;
- the risk to aquatic organisms.

The SANCO report for fluroxypyr (Fluroxypyr SANCO/11019/2011 rev 5 - 17 June 2011- 23 March 2017) 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 8.03.2011

Table 0.1-5: Information on minimum purity of fluroxypyr meptyl

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: Yes RMS: please refer to LoA

0.1.3.1 Florasulam

Table 0.1-6: 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 deadline for renewal of authorization (renewal)	31/12/2030
Date of final Commission (re-registration) deadline (Step 2)	31/12/2030
Current expiration of approval	31/12/2030
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 13.01.2015.

Table 0.1-7: Information on minimum purity of florasulam

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.

0.1.4 Regulatory history of the product

Not authorized yet.

0.2 zRMS conclusion

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

Efficacy section: all

Residues section: all

Environmental fate and behavior section: all

Ecotoxicology section: all

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

Efficacy section: none

Residues section: none

Environmental fate and behavior section: none

Ecotoxicology section: none

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:
Residues section: none

Residues section:
All uses/ GAPs are covered by established MRLs

Conclusions:

Identity section: The evaluators verified whether the co-formulants contained in plant protection product Turango 250 EC are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.
Based on the currently available MSDSs and other information provided by applicant on co-formulants, the product Turango 250 EC does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.
According to the current knowledge and available information none of the co-formulants in the plant protection product Turango 250 EC meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.
Detailed assessment of co-formulants according to Article 3 of Regulation (EU)2023/574 can be found in RR Part C of this submission (section 1.2.2).

Physical-chemical properties section:
Due to the hydrocarbon content and the results of kinematic viscosity (≤ 20.5 mm^2/s, measured at 40°C), the product shall be classified in Category 1, hazard statement H304. The relevant classification should be included on the label.
Due to emulsifiability results, the recommendations for ensuring thorough mixing before and during spray-

ing should be included on the label.
Due to the effectiveness of cleaning study results, the general cleanout with a tank cleaner should be recommended on the label.
In the accelerated storage and shelf-life stability study, the formulation was stored in commercial packaging (the bottles made of HDPE/PA) and the packaging remained stable during the storage, therefore, the proposed commercial packs of HDPE/PA are considered acceptable. According to SANCO/10473/2003-rev.5, for EC formulations extrapolation to other packaging is not acceptable so the HDPE/F and HDPE/EVOH packaging proposed in Part B4 were not accepted.

Efficacy section: All uses were accepted. CHR/H/CFF 250 EC is recommended for use against weeds at dose 0.4 L/ha and 0.5 L/ha at BBCH 21-32. Detailed assessment is presented in B3.

Mammalian toxicology section:
According to the toxicological properties classification of TURANGO 250 EC is: H302, H304, H315, H318. No risk for health operator, worker and bystander/resident.

Metabolism and residues: All uses are accepted.

- According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).
- EFSA recommends avoiding rotation with root and tuber crops (in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite).

Ecotoxicology section: All uses are accepted.
Risk assessment for aquatic plants (*M. spicatum*) has been not performed (insufficient data set - data gap). The new study the product TURANGO 250 EC and *Myriophyllum spicatum* should be performed. In order to answer the requirement from the zRMS a study for *Myriophyllum spicatum* has been included. The studies for formulation of Turango 250 EC for earthworms, *Folsomia candida* and *Hypoaspis aculeifer* was accepted by zRMS *only provisionally*. The toxicity endpoints were based on nominal concentration. At the end on the studies concentration of fluroxypyr-methyl was below 80%. The geometric mean measured concentration should be calculated over the duration of the test and used if the concentration falls under 80% of nominal. The Aplicant should complete the calculations of toxicity endpoints for earthworms and *Folsomia candida* and *Hypoaspis aculeifer* based on geometric mean measured concentration with a risk assessment for eartworms, *Folsomia candida* and *Hypoaspis aculeifer. The requirement of further data and calculations for the risk for aquatic plants and soil macroorganisms should be dealt at national level.*
Updated July 2024
To address the current data gap for *Myriophyllum spicatum* conducted by Applicant according to the OECD Guidelines. The new study for *Myriophyllum spicatum* with formulated product Turango 250 EC has been accepted by zRMS. Toxicity data and risk assessment for *Myriophyllum spicatum* was available for the PPP Turango 250 EC and a low risk was demonstrated for this species. The use Turango 250 EC according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1) with apply 5 meters buffer zone.

First tier chronic evaluation of the risk to adult bees exposed to Turango 250 EC resulted with ETR value above the trigger in weeds scenario indicating potentially unacceptable risk (Weeds/ BBCH 10-29 Weeds/ BBCH 30-39). No data enabling refinement of the risk was available. However, Turango 250 EC is herbicide, therefore it can be assumed that no weeds will be in the field after application.
On the basic information from SPe8 phrase in order to improve these risk assessments for cereals the following restrictions are necessary:
• Do not apply when flowering weeds are present/Erase flowering weeds before application
Nevertheless, since the EFSA Bee Guidance Document is yet to be implemented (2013), this result should be treated as indication of area that should be covered in the future, once the guidance document is officially noted and accepted. Further assessments from chronic exposure could be required at national level.

SPe8	SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply when flowering weeds are present. Remove weeds before flowering.

Updated April 2024

The Aplicant provided the calculations of toxicity endpoints for earthworms and *Folsomia candida* and *Hypoaspis aculeifer* based on geometric mean measured concentration with a risk assessment for eartworms, *Folsomia candida* and *Hypoaspis aculeifer.* The calculations were accepted by RMS. The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate). The TER_{LT} values for active substance and for product are above trigger value of 5, indicating an acceptable risk for earthworm and soil macro-organism for proposed use of the product **Turango 250 EC**.

Appendix 1 ALL intended uses

GAP rev. , date: 2021-01-13

PPP product name:		Formulation type:	EC [a, b]
product code:	CHR/H/CFF		
Active substance 1:	clopyralid	Conc. of as 1:	120 g/l [c]
Active substance 2:	fluroxypyr	Conc. of as 2:	120 g/l [c]
Active substance 3:	florasulam	Conc. of as 3:	10 g/l (c)
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	no		

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:**	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		e.g. g safener/synergist per ha [f]	

Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI)	F	dicotyle-donous weeds	Spray, medium sprayer	spring BBCH 21-32 ~~33~~	a)1 b)1	n/a	a) 0.4 - 0.5 l/ha b) 0.4 - 0.5 l/ha	a) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO) b) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO)	200-300 ~~400~~	n/a		**Eff. section:** accepted BBCH 21-32. and water volume: 200-300 L/ha **Ecotoxicology**: Uses are ~~not~~ accepted.
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	PL	Spelt *Triticum spelta* (3SPWC) Emmer wheat *Triticum dicoccum* (TRZDI) Einkorn wheat *Triticum monococcum (TRZMO)* Durum wheat *Triticum durum* (TRZDW) Spring Rye *Secale cereale* (SECCS)	F	~~Monocots and dicots~~ Dicoty-ledonous weeds	Spray, medium sprayer	BBCH 21-32 ~~33~~	a)1 b)1	n/a	a) 0.4 - 0.5 l/ha b) 0.4 - 0.5 l/ha	a) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO) b) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO)	200-300 ~~400~~		.	**Eff. section:** accepted BBCH 21-32 and water volume: 200-300 L/ha.. Only use against dicoty-ledonous should be recommended **Ecotoxicology:** Uses are ~~not~~ accepted..
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