

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: CHR/F/SCORPIO 325 SC

Product name(s): Clapton 325 SC, Scarp 325 SC

Chemical active substance(s):

Difenoconazole 125 g/L

Azoxystrobin 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Innvigo Sp. z o.o.

Submission date:

MS Finalisation date: 11/2025

Version history

When	What
11/2023	Dossier sent for evaluation
07/2025	Draft registration report provided by zRMS for commenting
11/2025	Final RR

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zRMS comments:

The text highlighted in grey was provided by the zRMS.

0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for authorization of CHR/F/SCORPIO 325 SC (Clapton 325 SC, Scarp 325 SC) containing 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/F/SCORPIO 325 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/F/SCORPIO 325 SC have been made using endpoints agreed in the EU review of Difenconazole, Azoxystrobin.

This document describes the specific conditions of use and labelling required for the registration of CHR/F/SCORPIO 325 SC (Clapton 325 SC, Scarp 325 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) Part B Sections 0-10, 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	PL CHR/F/SCORPIO 325 SC	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Difenconazole

Table 0.1-2: Summary of regulatory history of CAS No: 119446-68-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Reg. (EU) 2022/1480 Reg. (EU) 2023/2592
RMS	ES
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)	31/12/2023
Date of final Commission (re-registration) deadline (Step 2)	31/12/2023
Current expiration of approval	~~31/12/2023~~ 15/03/2026
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 the protection of aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate

The SANCO report for Difenoconazole (SANCO/830/08 – rev. 3) 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 EFSA Journal 2011;9(1):1967.

Table 0.1-3: Information on minimum purity of Difenoconazole

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equiv- alency report *, **
940 g/kg	Please refer to Part C- confidential information

* 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 Azoxystrobin

Table 0.1-4: Summary of regulatory history of CAS No: 119446-68-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Reg. (EU) 2018/155 Reg. (EU) 2019/291
RMS	AT
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2012

Status	
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 the protection of aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate

The SANCO report for Azoxystrobin (SANCO/11027/2011 Rev 3) 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 EFSA Journal 2010; 8(4):1542

Table 0.1-5: Information on minimum purity of Azoxystrobin

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 *, **
930 g/kg	Please refer to Part C- confidential information

* 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 (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information

The two-year storage stability study is missing. It must be provided to confirm the shelf-life for the PPP as requested by reg. 284/2013.

Section 3. Efficacy

The evaluation of the application of CHR/F/SCORPIO 325 SC resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical methods

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Section 6. Mammalian Toxicology

Classification: Carc. 2, H351, Eye Dam. 1, H318, Acute Tox. 4, H332, EUH208 Contains 1,2-Benzisothiazol-3(2H)-one. May produce an allergic reaction.

Operator: no PPE. Eye/face protection at the M/L step recommended due to the product classification.
Workers: Field, Low vegetables (Inspection, irrigation activity) -workwear
Low vegetables (except Inspection, irrigation activity), High ornamentals – gloves and workwear
Resident/Bystander: None (Field, Low vegetables), 5m of buffer zone (High ornamentals).

Section 7. Metabolism and Residues

Ornamental nursery plants, forest nursery plants, renewals afforestation, plantations of forest trees and energetic plants, pumpkin seeds, hemp seeds, flax seeds are not designated for dietary use in humans or live-stock. Therefore no further consideration is needed. As the establishment of a MRL for tobacco is not required, therefore no further consideration is needed.

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for azoxystrobin and difenoconazole as laid down in Reg. (EU) 396/2005 is not expected with exception of pumpkin seeds and hemp seeds – possible exceedance of azoxystrobin MRLs.

The chronic and the short-term intakes of azoxystrobin and difenoconazole residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland, zRMS agrees with the authorization of the intended uses with exception of pumpkin seeds and hemp seeds.

Considering that the residue results for rapeseed in the assessment refer to DALA in the range of 45-70 (62, 54, 58, 57, 54, 45, 70, 63), it is proposed to set PHI equal to 60 days for all oilseeds.

Considering that the residue results for sugar beet roots in the assessment refer to DALA 35 ±1, it is proposed to set PHI equal to 35 days.

Considering that the intervals between treatments in the studies provided exceed the min. recommended in GAP of 60/120 days, zRMS suggests limiting the use to one application for mustard seed, soybean, sunflower seed and linseeds.

The proposed uses are considered acceptable at max BBCH 55 for sunflower seeds, and soybean.

Section 8. Environmental Fate

The submitted exposure assessment in soil, groundwater and surface water was sufficient. Predicted environmental concentration in particular compartments were performed in accordance with EU requirements and FOCUS guidance.

Difenoconazole metabolite CGA 71019. In accordance with EFSA conclusion considering the PEC_{gw} for 1,2,4-triazole (CGA 71019) is to be below the 0.1 µg/L. No annual application is allowed.

This requirement would be fulfilled if formulation was applied every other or third year:

In case of **biennial application** – the PEC_{gw} values were below the trigger value of 0.1 µg/L for WOSR in autumn and spring application, SOSR, sugar beet, potato, carrot, maize and sunflower. For tobacco, ornamentals, (based on pome fruits and leafy vegetables) the safe use is demonstrated if formulation is applied **every third year**.

Section 9. Ecotoxicology

Based on the risk assessment in section of ecotoxicology it can be concluded that the revised proposed uses of CHR/F/SCORPIO 325 SC (Clapton 325 SC, Scarp 325 SC) poses acceptable risk to non-target organisms, except aquatic organisms. The risk assessment for difenoconazole needs to be completed and a new mixture toxicity assessment must be submitted. Particular precautions to reduce the environmental concentrations resulting from CHR/F/SCORPIO 325 SC (Clapton 325 SC, Scarp 325 SC) applications are required for aquatic organisms and terrestrial plants.

Section 10. Assessment of the relevance of metabolites in groundwater

The assessment of R234886 metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 (21 October 2021) performed by Applicant was accepted.

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

Section 9 Ecotoxicology: None All revised proposed uses

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

Residues: Not accepted for pumpkin seeds, hemp seeds — possible exceedance of MRL

Section 9 Ecotoxicology: All evaluated uses 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:

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Appendix 1 ALL intended uses

Clapton 325 SC, Scarp 325 SC
CHR/F/SCORPIO 325 SC
difenoconazole
azoxystrobin
-
-
-
Innvigo Sp. z o.o
Central ^(d)
neyes
fungicide

Formulation type: SC ^(a, b) , date: 2023-05-26

Conc. of as 1: 125 g/l ^(c)
Conc. of as 2: 200 g/l ^(c)
Conc. of as 3: -
Conc. of safener: - ^(c)
Conc. of syner-
gist: - ^(c)
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use- No. ^(e)	Mem- ber state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha ^(f)	ZRM's Conclu- sion
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. in- terval be- tween ap- plications (days)	kg or L product / ha a) max. rate per appl. b) max. to- tal 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 oilseed rape (BRSNW)	F	<i>Phoma lingam</i> , <i>Alternaria brassicae</i> , <i>Verticillium long- isporum</i>	Spray, medium sprayer	Autumn, spring BBCH 14- 22- -BBCH 31-55	a)1 b)2	min. 90/120 150	a) 0.9-1.0 l/ha b) 1.8-2.0 l/ha	a) 0.2925- 0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s./ha) b) 0.585-0.65 kg a.s./ha (AZX 0.36- 0.4 kg a.s./ha + DIF 0.225- 0.25 kg a.s./ha)	200- 400 300	n/a 60	1	apply every other year Aquatic or- ganisms – no safe
2	PL	Winter oilseed rape (BRSNW)	F	<i>Sclerotinia scleroti- orum</i> , <i>Botrytis cinerea</i> , <i>Alternaria brassicae</i> , <i>Verticillium long- isporum</i>	Spray, medium sprayer	Spring BBCH 61-69	a)1 b)1	n/a	a) 0.9-1.0 l/ha b) 0.9-1.0 l/ha	a) 0.2925- 0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s./ha) b) 0.2925- 0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s./ha)	200- 400 300	n/a 60	• SCLESC 1,0 L/HA • ALTEBA 1,0 L/HA • BOTRICI 0,9 L/HA	apply every other year Aquatic or- ganisms – no safe

[illegible]

Minor uses according to Article 51 (zonal uses)														
6	PL	Spring oilseed rape (BRSNS) (0401060), Mustard (3MUSC) (0401000), (0401080), <i>Papaver somniferum</i> (PAPSO) (0401000), (0401030), Soybean (GLXMA) (0401070), Sunflower (HELAN) (0401050), Pumpkin (CUUPE) (seed production only) (0401080), (0401100), Hemp/Flax (technical and seed production) (LIUT) (0401000), (0401140)	F	<i>Sclerotinia sclerotiorum</i> , <i>Alternaria brassicace</i> , <i>Leptosphaeria maculans</i> , <i>Alternaria brassicicola</i> , <i>Botrytis cinerea</i> , <i>Fusarium sp.</i> , <i>Fusarium oxysporum</i> , <i>Septoria glycines</i> , <i>Cercospora soja</i> , <i>Alternaria helianthin</i> , <i>Diaporthe helianthin</i> , <i>Golovinomyces cichoracearum</i> , <i>Alternaria alternata</i> , <i>Golovinomyces orontii</i> , <i>Melampsora lini</i> , <i>Septoria cannabis</i> ,	Spray, medium sprayer	Autumn, spring OSR, mustard, poppy, flax, hemp, sunflower BBCH 14-29 14-22 or BBCH 31-69 Soybean BBCH 14-22; BBCH 31-39 BBCH 50-55 Pumpkin BBCH 50-69 For sunflower and soybean allowed for treatments at max BBCH 55	a)1 b)2 Only for oilseed rape 2 applications are accepted; For the rest only 1 is accepted	min. 90/120 150	a) 0.9-1.0 l/ha b) 1.8-2.0 l/ha	a) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s./ha) b) 0.585-0.65 kg a.s./ha (AZX 0.36-0.4 kg a.s./ha + DIF 0.225-0.25 kg a.s./ha)	200-400	n/a 60		apply every other year Not accepted for pumpkin seeds, hemp seeds – possible exceedance of MRL Only for oilseed rape 2 appl. are accepted, for the rest 1 appl. is accepted Mammals: soybean – no safe – BBCH 40-49 Pumpkin – no safe- BBCH 10-49 Aquatic organisms – no safe

7	PL	<i>Brassica napus</i> subsp. <i>rapifera</i> (BRSNA)((roots only), <i>Cichorium intybus</i> (CICIN) (roots only), <i>Beta vulgaris</i> subsp. <i>vulgaris</i> (BEAVD), <i>Armoracia rusticana</i> (ARWLA), <i>Apium graveolens</i> var. <i>rapaceum</i> (APUGR)	F	<i>Alternaria</i> sp, <i>Erysiphe heraclei</i> , <i>Sclerotinia sclerotiorum</i> , <i>Septoria apiicola</i> , <i>Botrytis cinerea</i> , <i>Erysiphe betae</i> , <i>Cercospora beticola</i> <i>Uromyces beticola</i> , <i>Alternaria brassicicola</i> , <i>Erysiphe cruciferarum</i> , Turnip mosaic virus, <i>Albugo candida</i> , <i>Leptosphaeria maculans</i> , <i>Botryotinia fuckeliana</i> , <i>Alternaria radicina</i>	Spray, medium sprayer	Spring BBCH 39-49	a)1 b)1	n/a	a) 0.8-1.0 l/ha b) 0.8-1.0 l/ha	a) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s./ha) b) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s./ha)	200-400	n/a 35		apply every other year Aquatic organisms – no safe
8	PL	Ornamental nursery plants, forest nursery plants, renewals, afforestation and plantations of forest trees	F	<i>Podosphaeras p.</i> , <i>Gymnosporangium</i> sp., leaf spot, <i>Lophodermium seditiosum</i> , <i>Diplocarpon rosae</i> , <i>Colletotrichum gloeosporioides</i> , diseases caused by soil pathogens	Spray, medium sprayer	Spring the first symptoms of infection Ornamental nursery plants, forest nursery plants BBCH up to 39 Others BBCH > 40	a)1 b)2	14	a) 1.0 l/ha b) 2.0 l/ha	a) 0.325 kg a.s./ha (AZX 0.2 kg a.s./ha + DIF 0.125 kg a.s./ha) b) 0.65 kg a.s./ha (AZX 0.4 kg a.s./ha + DIF 0.25 kg a.s./ha)	300-1200	n/a		apply every third year Mammals – no safe – BBCH ≥40 Aquatic organisms – no safe
9	PL	Energetic plants, <i>Salix viminalis</i> (SAXVI), <i>Wicker</i> (ISAXG)	F	<i>Podosphaeras p.</i> , <i>Gymnosporangium</i> sp., leaf spot, <i>Lophodermium seditiosum</i> , <i>Diplocarpon rosae</i> , <i>Colletotrichum gloeosporioides</i> , diseases caused by soil pathogens	Spray, medium sprayer	Spring the first symptoms of infection BBCH>40	a)1 b)2	14	a) 0.8 l/ha b) 1.6 l/ha	a) 0.260 kg a.s./ha (AZX 0.16 kg a.s./ha + DIF 0.100 kg a.s./ha) b) 0.52 kg a.s./ha (AZX 0.32 kg a.s./ha + DIF 0.200 kg a.s./ha)	300-1200	n/a		apply every third year Mammals – no safe – BBCH up to 40 Aquatic organisms – no safe

10	PL	<i>Nicotiana tabacum</i> (NIOTA)	F	<i>Alternaria spp., Golovinomyces cichoracearum</i>	Spray, medium sprayer	Spring the first symptoms of infection BBCH≥40	a)1 b)2	14	a) 1.0 l/ha b) 2.0 l/ha	a) 0.325 kg a.s./ha (AZX 0.2 kg a.s./ha + DIF 0.125 kg a.s./ha) b) 0.65 kg a.s./ha (AZX 0.4 kg a.s./ha + DIF 0.25 kg a.s./ha)	300-1200	n/a		apply every third year Birds – no safe – BBCH up to 29 Mammals – no safe – BBCH 10-39 ~~Aquatic organisms – no safe~~
Minor uses according to Article 51 (interzonal uses)														
11														
12														

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

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