

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: Diflufenikan 500 SC

Product name(s): -

Chemical active substance:

diflufenican, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

(Art. 33 - Extension of authorisation for professional user)

Applicant: Pestila Sp. z o.o.

Submission date: July 2024

MS Finalisation date: March 2025; July 2025

Version history

When	What
10.2023	ZRMs evaluated dRR submitted by Applicant
01.2024	The final Registration Report
04.2024	Corrections in line to MRiRW comments were made
06.2024	Corrections in line to MRiRW comments were made
07.2024	Label extension acc. Art. 33 Reg (EC) 1107/2009 for professional user
02.2025	zRMS assessment of Part B1-2,4 update (2-year stability study)
03.2025	ZRMs assessed the possibility of the extension of authorisation of use on winter barley
07.2025	The final Registration Report

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for the registration of Diflufenikan 500 SC, containing active substance diflufenican, 500 g/L in Poland. This evaluation is required since the product is a new formulation and has not yet been authorised in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in the Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Diflufenikan 500 SC where that data has not been considered in the EU review. Otherwise, assessments for the safe use of Diflufenikan 500 SC have been made using endpoints agreed in the EU review of diflufenican.

This document describes the specific conditions of use and labelling required for Poland for the registration of Diflufenikan 500 SC.

This is application to extend the authorisation of the plant protection product (PPP) already authorised in Poland, to be used in winter barley has not been covered by that authorisation yet.

The risk assessment conclusions are based on the already existing registration of the PPP. The following sections of Registration Report, Part B were prepared on basis of new data:

Section B0

Section B3

Section B5 (use in winter barley has been already assessed and approved, see point 5.1)

Section B6 (use in winter barley has been already assessed and approved, see Table 6.1 4 Critical uses and overall conclusion of exposure assessment)

Section B7 (use in winter barley has been already assessed and approved see Table 7.1 1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable))

Section B8

Section B9

Assessments for the safe use of Diflufenikan 500 SC have been made using endpoints agreed in the EU reviews of azoxystrobin.

With reference to Part B Section 3 trials for winter barley have been provided by the Applicant with this application. All trials were established in N-EU zone and performed according to intended GAP table. No further studies are required.

1.1 Application background

This application was submitted by Pestila Spółka z ograniczoną odpowiedzialnością (hereinafter referred as Pestila Sp. z o. o.)

This is the application for registration of plant protection product under working name of Diflufenikan 500 SC according to Article 33 of Regulation 1107/2009. Diflufenikan 500 SC is a suspension concen-

trate (SC), containing 500 g/L of diflufenican to be used as herbicide to protect winter cereals.

1.2 Letters of Access

Letter of Access is submitted. See Appendix 3.

1.3 Justification for submission of tests and studies

Author	Year	Title Report number Source GLP Published	Justification for submitting
Section 1: Identity			
Section 2: Physical and chemical properties,			
Section 4: Further information			
Kupiec J.	2022	DIFLUFENIKAN 500 SC. Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Report No BF – 24/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Published: no	Regarding Commission Regulation (EU) No. 284/2013 of 1 st of March 2013 it was assess that in case when the new recipe of the generic plant protection product is developed it is necessary to generate physical and chemical properties in order to check if it fulfils FAO specification, is safe, stable etc. The range of studies performed for Diflufenikan 500 SC are those recommended for SC formulation.
Ołowski G.	2022	DIFLUFENIKAN 500 SC. Determination of explosive properties. Report No BW-15/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Published: no	
Flasińska P.	2022	Diflufenikan 500 SC.Determination of flash point, auto-ignition temperature and oxidizing properties. Report No BWC-44/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Published: no	
Section 3: Efficacy Data and Information			
Kukuła A.	2021	Efficacy of H-01-2020 for the control of weeds in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0821-1 GEP: Yes Published: No	In accordance with the requirements of Commission Regulation (EU) No. 284/2013 of 1st of March 2013 “ <i>The data supplied must be sufficient to permit an evaluation of the plant protection product to be made.</i> ” Formulation of Diflufenikan 500 SC was not evaluated, so it was necessary to confirm efficacy and selectivity.
Kukuła A.	2021	Efficacy of H-01-2020 for the control of weeds in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0821-2 GEP: Yes Published: No	
Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter wheat. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland;	

		Report No.: 001GP202103 GEP: Yes Published: No	
Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter wheat. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 001GP202104 GEP: Yes Published: No	
Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter barley. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 002GP202102 GEP: Yes Published: No	
Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter barley. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 002GP202103 GEP: Yes Published: No	
Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter triticale. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 003GP202102 GEP: Yes Published: No	
Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter triticale. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 003GP202103 GEP: Yes Published: No	
Szemendera A.	2023	Efficacy of H-01-2020 in weed control in winter wheat, Poland 2022; Fertico Sp. z o.o., Poland; Report No.: 347_01_F22_060 GEP: Yes Published: No	
Kukuła A.	2021	Selectivity of H-01-2020 in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0822-1 GEP: Yes Published: No	
Kukuła A.	2022	Selectivity of H-01-2020 in winter wheat. 2022; AGRECO Sp. z o.o., Poland; Report No.: 22PRO0974-3 GEP: Yes	

		Published: No	
Kukuła A.	2022	Selectivity of H-01-2020 in winter wheat. 2022; AGRECO Sp. z o.o., Poland; Report No.: 22PRO0974-4 GEP: Yes Published: No	
Szemendera A.	2023	Selectivity of H-01-2020 applied in control of weeds in winter wheat, Poland 2022; Fertico Sp. z o.o., Poland; Report No.: 348_01_F22_061 GEP: Yes Published: No	
Figurski R.	2023	Selectivity of H-01-2020 in winter rye. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202201 GEP: Yes Published: No	
Figurski R.	2023	Selectivity of H-01-2020 in winter rye. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202202 GEP: Yes Published: No	
Figurski R.	2023	Selectivity of H-01-2020 in winter rye. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202203 GEP: Yes Published: No	
Figurski R.	2023	Selectivity of H-01-2020 in winter triticale. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202204 GEP: Yes Published: No	
Figurski R.	2023	Selectivity of H-01-2020 in winter triticale. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202205 GEP: Yes Published: No	
Figurski R.	2023	Selectivity of H-01-2020 in winter triticale. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202206 GEP: Yes Published: No	
Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-3 GEP: Yes Published: No	
Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-4 GEP: Yes Published: No	

Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-1 GEP: Yes Published: No	
Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-2 GEP: Yes Published: No	
Section 5: Analytical Methods			
Kupiec J.	2022	DIFLUFENIKAN 500 SC. Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Report No BF – 24/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Published: no	Regarding Regulation 284/2013 of 1 st of March 2013 it was assess that in case when the new recipe of the generic plant protection product is developed it is necessary to generate analytical methods for determination of active substances and relevant impurities in the formulation in order to check if it fulfils FAO specification, is safe, stable etc.
Section 8: Environmental Fate			
Hara-Skrzypiec A.	2022	Diflufenikan 500 SC Calculation of predicted environmental concentrations of diflufenican and its metabolites in groundwater using the FOCUS groundwater scenarios (FOCUS PEARL, FOCUS PELMO) Company Report No: EST/22/2022 ESTICON Sp. z o.o. GLP: No Published: No	Modelling of PECgw and PECsw according to EU and national requirements is always required.
Hara-Skrzypiec A.	2022	Diflufenikan 500 SC Calculation of Predicted Environmental Concentrations of diflufenican and its metabolites in surface water using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/21/2022 ESTICON Sp. z o.o. GLP: No Published: No	
Section 9: Ecotoxicology			
Czarnecka M	2022	Diflufenikan 500 SC <i>Daphnia magna</i> , Acute Immobilisation Test Study Code: W-07-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	In accordance with the requirements of Commission Regulation (EU) No. 284/2013 of 1st of March 2013 testing of the plant protection product shall be necessary where its toxicity cannot be predicted on the basis of data on the active substance.
Czarnecka M	2022	Diflufenikan 500 SC <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>), Growth inhibition test Study Code: W-08-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Czarnecka M	2022	Diflufenikan 500 SC <i>Lemna gibba</i> CPCC 310 Growth inhibition test Study Code: W-09-22 Source: Institute of Industrial Organic Chemistry Branch Pszczyna, Poland GLP Unpublished	
Czarnecka M	2022	Diflufenikan 500 SC Water-sediment <i>Myriophyl-</i>	

		<i>lum spicatum</i> toxicity test Study Code: W-06-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Kulec- Płoszczyca E	2022	Diflufenikan 500 SC Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test Study Code: B-99-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Kulec- Płoszczyca E	2022	Diflufenikan 500 SC Bumblebees (<i>Bombus</i> spp.), Acute Oral Toxicity Test Study Code: B-100-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Kulec- Płoszczyca E	2022	Diflufenikan 500 SC Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Study Code: B-101-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Kulec- Płoszczyca E	2022	Diflufenikan 500 SC Bumblebees (<i>Bombus</i> spp.), Acute Contact Toxicity Test Study Code: B-102-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Pieczka P	2022	Diflufenikan 500 SC Earthworm reproduction test Study Code: G-89-21 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Pieczka P	2022	Diflufenikan 500 SC Soil Microorganisms: Nitrogen Transformation Test Study Code: G-90-21 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Pieczka P	2022	Diflufenikan 500 SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study Code: G-92-21 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	
Pieczka P	2022	Diflufenikan 500 SC Terrestrial Plant Test: Vegetative Vigour Test Study Code: G-91-21 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided

for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	Diflufenikan 500 SC
Product name in MS	Danubis 500 SC
Authorization number	R-99/2024
Function	Herbicide.
Applicant	Pestila Sp. z o. o.
Active substance(s) (incl. content)	Diflufenican 500 g/L
Formulation type	Suspension Concentrate [SC]
Packaging	250mL, 0.5L, 1L, 5L, 10L, 20L bottles, cannisters HDPE, HDPE/PA (COEX), fHDPE and 220L, 1000L drums and containers HDPE professional
Coformulants of concern for national authorizations	Not applicable.
Restrictions related to identiy	Not applicable.
Mandatory tank mixtures	Not applicable.
Recommended tank mixtures	Not applicable.

2.2 Conclusion

Diflufenikan 500 SC can be granted in line to accepted GAP table and label project in Poland.

Efficacy section: All uses claimed in GAP table are accepted (winter: wheat, triticale and rye). **Danubis 500 SC can be extended for use on winter barley** on the basis on submitted additional documentation (4 selectivity trials carried out on winter barley in Poland) by Applicant.

Mammalian toxicology:

According toxicological properties DUNBIS 500 SC is unclassified. Contains 1,2-benzisothiazol-3(2H)-on. May produce an allergic reaction. [EUH208]. No risk for operator, worker, bystander/resident. Buffer zone 2-3m.

Physical and chemical properties section:

~~2 years ambient shelf life study is ongoing and the results should be available in November 2024.~~ No data gaps – the 2-year ambient shelf life study was submitted and results were assessed and accepted.

Fate and Ecotoxicology section: Proposed uses are accepted. **Danubis 500 SC can be extended for use on winter barley.**

Conclusion:

1. Based on PEC/RAC calculations, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses for Diflufenican 500 SC, provided that following risk mitigation measures are

taken into account:

- a vegetative buffer strip of 5 m to surface water bodies is required when conventional spraying techniques are applied.

2. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agriculture area.

Metabolism and residues

Proposed uses are accepted.

2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

2.4 Classification and labelling


Adding the new major crop: winter barley, does not require additional calculations regarding classification of product. The previous calculations presented by the applicant fully cover the addition of a new crop.

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P280 - Wear protective gloves, protective clothing. P391 - Collect spillage.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazol-3(2H)-on. May produce an allergic reaction. [EUH208]

Special rule for labelling of plant protection product (PPP):

EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH208	Contains 1,2-benzisothiazol-3(2H)-on. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect a vegetated buffer zone of 5m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agriculture area.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	None. Recommended: workwear (arms, body and legs covered) and gloves during mixing/loading and during application.
Worker protection:	
-	None. Recommended: workwear (arms, body and legs covered) and gloves when inspecting the treated crops.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect a vegetated buffer zone of 5m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agriculture area.
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
SPe3	To protect aquatic organisms respect a vegetated buffer zone of 5m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agriculture area.	1

2.6 Intended uses (only NATIONAL GAP)

GAP rev.2, date: 2024-07-30

PPP (product name/code): Di flufenikan 500 SC
Active substance 1: di flufenican
Safener: n.a.
Synergist: n.a.
Applicant: Pestila Sp. z o.o.
Zone(s): Central Zone ^(d)
Verified by MS: no

Formulation type: SC ^(a, b)
Conc. of as 1: 500 g/l ^(c)
Conc. of safener: n.a. ^(c)
Conc. of synergist: n.a. ^(c)
Professional use: ☒
Non professional use: ☐

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					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	Poland	Winter wheat, Winter triticale Winter rye Winter barley	F	<p>Susceptible weeds (0.2L/ha): Shepherd's purse <i>Capsella bursa-pastoris</i> CAPBP; Field pansy <i>Viola arvensis</i> VI-OAR; Bird's-eye speedwell VERPE <i>Veronica persica</i></p> <p>Susceptible weeds (0.3L/ha): Shepherd's purse <i>Capsella bursa-pastoris</i> CAPBP; Cornflower <i>Centaurea cyanus</i> CENCY; Purple deadnettle <i>Lamium purpureum</i> LAMPU; Common chickweed <i>Stellaria media</i> STEME; Field pansy <i>Viola arvensis</i> VI-OAR; Bird's-eye speedwell VERPE <i>Veronica persica</i></p> <p>Moderately susceptible weeds (0.2L/ha): Silky apera <i>Apera spica-venti</i> APESV; Purple deadnettle <i>Lamium purpureum</i> LAMPU Common chickweed <i>Stellaria media</i> STEME; Small-flower geranium GERPU <i>Geranium pusillum</i></p> <p>Moderately susceptible weeds (0.3L/ha): Silky apera <i>Apera spica-venti</i> APESV; Small-flower geranium GERPU <i>Geranium pusillum</i> Wild chamomile MATCH <i>Matricaria chamomilla</i></p> <p>Moderately resistant weeds</p>	broadcast spraying	BBCH 00-29 Autumn application pre- and post emergence	1 a) 1 b) 1	N/A	0.2 – 0.3 L/ha a) 0.3 L/ha b) 0.3 L/ha	100-150 g diflufenican a) 150 g diflufenican b) 150 g diflufenican	100-400 L/ha	not relevant	not relevant

			(0.2L/ha): Cornflower <i>Centaurea cyanus</i> CENCY										
			Tolerant weed (0.2 L/ha): Wild chamomile MATCH <i>Matricaria chamomilla</i>										

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

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.

(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.

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

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 homogenous whitish liquid of characteristic odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 600 °C. In aqueous solution, it has a pH value around 7.91 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 4 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.05% to 0.3%.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

No results of the preliminary range-finding tests are presented since no screening trials were carried out. However, the active substance of DiFlufenikan 500 SC, namely diflufenican, have been commonly used in agricultural practice for many years.

The applicant carried out efficacy trials on winter wheat (5), winter barley (2), winter triticale (2) in Poland in 2020-2023 (for more information please refer to Part B, Section 3 Efficacy Data and Information). Nevertheless, it is possible to use extrapolation tables, according to Polish guidelines. Therefore, the applicant applies for the aforementioned crops to be registered in Poland, namely: winter wheat, winter triticale and rye as well as winter barley. Required selectivity trials have been presented in Part B, Section 3 Efficacy Data and Information.

No phytotoxicity symptoms caused by DiFlufenikan 500 SC at the proposed doses rate of 0.2-0.3 L/ha were recorded in all trials.

Evaluation of extending registration to winter barley:

This document was prepared by Applicant for the extension of registration DANUBIS (product code: DiFlufenican 500 SC) for use on winter barley. Danubis is already registered on the Polish market (R-99/2024 dated 26.06.2024) for use on winter wheat, winter triticale and winter rye against weeds. Previous assessment is still valid. All necessary information's about tested plant protection product, active substance, studied weeds, reference products, etc. were correctly presented. In Poland 74 PPPs with diflufenican as an active compound (single or in tank mix) are registered for use in winter barley for control weeds (in line with plant protection products search engine).

Minimum effective dose:

The active substance diflufenican is the active ingredient of many herbicides and in consequence the effective doses are known and well proven.

EPPO PP1/225 states that in the case of multiple target pests 'Information is required for a range of targets which are the most important, and for which control provides the major agricultural benefit. It should be noted that where the proposed use is across a substantive geographical area such as an authorization zone (as defined in PP 1/278 Principles of zonal data production and evaluation), the major target species and/or the major crop may vary and there may be differences in population pressures. Therefore, particular consideration should be given to trials location.' Therefore, the applicant properly assessed the minimum effective dose of the 'DiFlufenikan 500 SC'.

The trials submitted to support the MED of 'Diflufenikan 500 SC' are the same as the efficacy trials described under section 3.2.3. (Efficacy tests). All the MED data were produced in the North-East EPPO zone (PL-9). The zRMS considers that a minimum population of 5 weeds/m² or 2% ground cover is required for a trial to be considered sufficiently challenging and valid.

Following weed species were studied during trials: APESV (5), BRSNN (2), CAPBP (4), CENCY (4), CHEAL (1), CIRAR (1), GERPU (3), LAMPU (4), MATCH (3), MATIN (2), PAPRH (3), POAAN (1), STEME (4), VERHE (1), VERPE (2) and VIOAR (5).

During the efficacy studies Applicant used 3 different doses of herbicide – 'Diflufenikan 500 SC': 0,15 l/ha (0.5N), 0.20 l/ha (lower N) and 0.30 l/ha (N dose). So, in the appropriate research of efficacy were tested different doses and to register was chosen the lowest effective 0.20 l/ha – which should be use in the case of lower infestation and good weather conditions and dose 0.3 L/ha which should be use in the case of high infestation and/or worse weather conditions.

Applicant showed that the reduced dose (0.20 l/ha) is characterized by similar efficacy to the higher dose (0.30 l/ha). A reduction in the registered dose is proposed due to unacceptable risk to aquatic organisms for the higher dose of 0.30 l/ha (which may occur).

The 0.2-0.3 L/ha dosage of Diflufenikan 500 SC provided the optimum overall control (higher dose is to be used when demanding weed species occur or infestation level is high) and should be considered as effective against dicotyledonous and monocotyledonous weeds in winter wheat, winter rye and winter triticale, for which activity of 'Diflufenikan 500 SC' is claimed.

Evaluation of extending registration to winter barley:

Previous assessment is still valid for the extension on winter barley, especially if Applicant did not submit any new efficacy trials carried out on winter barley or other winter cereals (like wheat, triticale or rye). List of accepted weed species and their scale of sensitivity not require any changes. So, MED dose for previous accepted winter cereals (wheat, triticale and rye) is also recommended for winter barley as the most effective. In accordance with the Polish harmonization meetings no efficacy trials are required for the extrapolation of results from winter cereal to winter barley. Only 3-4 selectivity trials carried out in PL on winter barley are needed. Applicant properly presented 4 valid selectivity trials carried out in PL on winter barley, so possibility of the extension of registration on winter barley is accepted by ZRMs.

Efficacy

All details about efficacy methodology used during efficacy trials (9 in total) are presented above by Applicant. The trials were performed in the North-East EPPO zone (PL-9) in varied soil, environmental and climatic conditions with the use of different agricultural practice. The experiment was established on a set of complete randomized blocks in 4 replications, statistical methods and observation dates were applied. The reports include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.

The number of efficacy of the product presented in this dossier is in accordance with the basic number of trials defined in EPPO PP/226 (6–15 trials) for winter cereals. For winter wheat Applicant submitted only 5 trials carried out in 3 different growing seasons (2020/2021; 2021/2022 and 2022/2023). However, in the opinion of ZRMs reduction number from 6 to 5 can be acceptable. 80 PPP with diflufenican as an active substance are on the Polish market, its efficacy is known. Diflufenican (DFF) is now a substance that is very commonly prevalent in the protection of cereals against weeds. In the 2022 agricultural crop protection program, the most popular herbicide chemicals are diflufenican and flufenacet used singly and in mixtures. Diflufenican is a contact-active substance. After application, it remains on the soil surface for a long time, producing a thin layer that has a contact effect on emerging young, actively growing weeds. Protection time after herbicide application is about 8 weeks. Diflufenican remains active in the soil for many weeks after treatment, resulting in the maintenance of high herbicidal efficacy even afterwards.

The results showed that as the dose increases, the effectiveness of the product increases. And the results proved to be quite consistent. Winter triticale and winter rye were characterized by not enough number of trials. However, Applicant submitted 3 selectivity trials for those crops. So, in the opinion of ZRMs extrapolation of results is possible. Especially since a group of plants (winter cereals) and not individual crops was used to classify weeds.

The Applicant did not provide any scale of efficacy/susceptibility of studied weeds. So, Evaluator applied the efficacy scale of efficacy/susceptibility weeds due to existing Member State requirements for expressing levels of control for weeds and the practice of preparations by Polish farmers:

- S (susceptible) > 85% (within each trial the average must be higher than 85%)
- MS (moderately susceptible) 70-85%,
- MT (moderately tolerant) 60-70%,
- T (tolerant) < 60%.

We are dealing with the active substances used commonly for many years in many countries. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations. Only trials with appropriate level of infestation (5 weeds/m²) were used for evaluation.

According to PP 1/226, major weeds should be supported with at least 6 trials and minor weeds with at least 2 trials. However, according to Polish rules for major weeds at least 4 trials are required and for minor – 2 trials. Most of the studied weed species did not meet the minimum necessary number of tests.

The weeds were treated at BBCH stage 10-16 in POST application. The water volume ranged from 300 to 400 l/ha.

Applicant correctly presented results. All studied weed species were characterized by enough number of trials and level of infestation.

Early post-emergence uses on winter cereals crops against accepted weeds species (on the basis of 9 trials: winter wheat-5 trials, winter barley – 2 trials, winter triticale – 2 trials):

- ✓ **APESV** – major weed – 5 trials – MT at 0.15 L/ha and MS at 0.2 and 0.3 L/ha
- ✓ **CAPBP** – minor weed – 4 trials – S at all studied doses (0.15 L/ha; 0.2 L/ha and 0.3 L/ha)
- ✓ **CENCY** – major weed – 4 trials – MS at 0.15 L/ha; MT at 0.2 L/ha and S at 0.3 L/ha.
- ✓ **GERPU** – minor weed – 3 trials – MT at 0.15 L/ha and MS at 0.2 and 0.3 L/ha.
- ✓ **LAMPU** – minor weed – 4 trails – MS at 0.15 and 0.2 L/ha and S at 0.3 L/ha
- ✓ **MATCH** – minor weed – 3 trials – MT at 0.15 L/ha; T at 0.2 L/ha and MS at 0.3 L/ha
- ✓ **STEME** – minor weed – 4 trials -MS at 0.15 and 0.2 L/ha and S at 0.3 L/ha
- ✓ **VERPE** – minor weed – 2 trials – MS at 0.15 L/ha and S at 0.2 and 0.3 L/ha
- ✓ **VIOAR** – major weed – 5 trials – MS at 0.15 L/ha and S at 0.2 and 0.3 L/ha

The most effective dose for most studied weed species for post-emergence use was dose: 0.3 L/ha. However, dose 0.2 L/ha was characterized only less effective than dose 0.3 L/ha.

Following major weeds should be excluded from GAP table and label project due to not enough trials (at least 4 are required): BRSNN (2 trials), MATIN (2 trials), PAPRH (3 trials).

Weeds species represented only by one trial were also excluded from GAP table and label project: CHEAL, CIRAR, POAAN, VERHE.

In Polish label following weeds species can be included for winter wheat, winter triticale and winter rye and winter barley:

- **Dose 0,2 L/ha:** *Susceptible weeds:* CAPBP, VERPE, VIOAR; *Moderately susceptible weeds:* APESV, GERPU, LAMPU and STEME; *Moderately tolerant weeds* CENCY; *Tolerant weeds:* MATCH.

- **Dose 0,3 L/ha:** *Susceptible weeds:* CAPBP, CENCY, LAMPU, STEME, VERPE, VIOAR; *Moderately susceptible weeds:* APESV, GERPU, MATCH.

This plant protection product 'Diflufenikan 500 SC' can be used on winter cereals (wheat, triticale and rye) against weed species included in GAP table and label project. Product can be use pre- and post-emergence at BBCH 00-29 at autumn application.

The trials are acceptable for PL (N-E EPPO zone). In the opinion of ZRMs submitted documentation will be not sufficient for CMS from other EPPO zone. However, final decision is left to CMS.

Evaluation of extending registration to winter barley:

Previous assessment is still valid for the extension on winter barley, especially if Applicant did not submit any new efficacy trials carried out on winter barley or other winter cereal (like wheat, triticale or rye). List of accepted weed species and their scale of sensitivity not require any changes. In accordance with the Polish harmonization meetings – no efficacy trials are required for the extrapolation of results from winter cereal to winter barley. Only 3-4 selectivity trials carried out on winter barley are needed. Applicant properly presented 4 valid selectivity trials carried out in PL on winter barley, so possibility of the extension of registration on winter barley is accepted by ZRMs.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Diflufenican belongs to the pyridinecarboxamide group. Applied early post-emergence, diflufenican is effective on some important broadleaf weeds. This compound typically affects susceptible weeds at the early stages.

Diflufenican is persistent in soil (DT_{50} = 224 days) thus a prolonged exposure to weed populations may occur. The herbicidal effects of diflufenican are primarily due to its inhibition of carotenoid biosynthesis at the phytoene de-saturase step (PDS).

Due to the primary target site and the chemical subgroup, diflufenican is classified as a HRAC group F1 herbicide (inhibition of carotenoid biosynthesis at the phytoene desaturase step (PDS)). In the WSSA resistance classification system the pyridinecarboxamides are classified as group 12. The other chemical groups in HRAC group F1 are: Pyridazinones and other.

Some naturally occurring weed biotypes resistant to F1 herbicides may exist through normal genetic variability in any weed population. The resistant biotypes are unusual. A PDS mutation leading to resistance has been identified. Also, non-target-site resistance has been suggested.

HRAC group F1 herbicides are used for weeding control in agricultural crops for more than 20 years. Since the first years these products were used no weeds resistant to Carotenoid biosynthesis inhibitors have been reported in central Europe.

The applicant has not provided a resistance risk assessment in accordance with EPPO PP 1/213.

Resistance to diflufenican has been reported in 3 weed species, consisting of 5 individual cases of resistance being observed. These include the 4 stated above by the applicant along with a more recent observation in *Senecio vernalis* in Israel in 2014. The full list of resistance cases to diflufenican are shown in the table below, taken from <http://www.weedscience.org>:

Reported cases of resistance to diflufenican

#	Year	Species	Country	MOAs	Actives	Contacts
1	1998	<i>Raphanus raphanistrum</i>	Australia (Western Australia)	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12)	chlorsulfuron, diflufenican, metosulam	Abul Hashem
2	2006	<i>Raphanus raphan-</i>	Australia (South Austral-	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12),	2,4-D, diflufenican, MCPA,	Christopher Preston,

#	Year	Species	Country	MOAs	Actives	Contacts
		<i>istrum</i>	ia)	Synthetic Auxins (O/4)	triasulfuron	Peter Boutsalis
3	2011	<i>Sisymbrium orientale</i>	Australia (Victoria)	Carotenoid biosynthesis inhibitors (F1/12)	diflufenican	Christopher Preston, Peter Boutsalis
4	2010	<i>Raphanus raphanistrum</i>	Australia (Western Australia)	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12), EPSP synthase inhibitors (G/9), Synthetic Auxins (O/4)	2,4-D, chlorsulfuron, diflufenican, glyphosate, imazethapyr, MCPA, metosulam, sulfometuron-methyl	Stephen Powles, Michael Ashworth
5	2014	<i>Senecio vernalis</i>	Israel	ALS inhibitors (B/2), Carotenoid biosynthesis inhibitors (F1/12), Photosystem II inhibitors (C1/5), PPO inhibitors (E/14), PSII inhibitor (Ureas and amides) (C2/7)	carfentrazone-ethyl, diflufenican, diuron, imazamox, metribuzin	Baruch Rubin, Maor Matzrafi

Diflufenican has been authorised as an herbicide in Europe for decades and despite its widespread use in cereals, no resistance to this active substance has yet been reported in Europe. There is currently no resistance to any Group F1 herbicides in Europe. Additionally, no cross resistance to diflufenican is known.

The only target weed with reported resistance to diflufenican is RAPRA, although this was reported outside of Europe. *Senecio vernalis* is also of the same genus as the target weed SENVU.

The zRMS would consider that inherent risk of resistance developing to diflufenican to be low. Some of the target weeds e.g. STEME and PAPRH have an inherently high risk of developing resistance; however, there has been no resistance to any of the target weeds except RAPRA. The resistance to this weed was outside of Europe and this is not usually considered to be a high risk weed. 'Diflufenican 500 SC' is restricted to 1 use per season and there are other herbicides that can control the target weeds in cereals, along with non-chemical control such as cultivation or rotation.

Overall, the zRMS considers that the risk of resistance developing to diflufenican from the proposed use of 'Diflufenican 500 SC' is low. No specific resistance management strategy is considered necessary for the PL label.

ZRMs approved the proposed label provision about strategies to minimize the risk of occurrence and the development of weed resistance against diflufenican.

To minimize the risk of occurrence and development of weed resistance to herbicides, according to Good Agricultural Practice:

- ✓ follow strictly the directions on the crop protection product label - apply the product at the recommended dose, at the recommended time to ensure optimal weed control,
 - ✓ adjust the choice of herbicide and the decision to carry out the treatment to the prevailing (possibly potential) weed infestation, taking into account the dominant species and pest thresholds,
 - ✓ use a rotation of herbicides (active substances) with different mechanisms of action,
 - ✓ use a mixture of herbicides (active substances) with different mechanism of action,
 - ✓ use in rotation and/or mixture herbicides acting on several life processes of weeds (with different mechanism of action),
 - ✓ apply an herbicide with a given mechanism of action only once during the growing season of the crop,
 - ✓ adjust tillage operations to field conditions, especially to the type and severity of weeds,
 - ✓ use various methods of weed control, including crop rotation, etc.,
 - ✓ use certified seed,
 - ✓ clean agricultural machinery to prevent the transfer of weed propagating material to other sites,
 - ✓ inform the permit holder of unsatisfactory weed control,
- for more information, contact your advisor, the permit holder or the permit holder's representative.

Evaluation of extending registration to winter barley:

Previous assessment is still valid for the extension on winter barley. The risk of resistance development is influenced more by the frequency and type of herbicide application than by the crop itself (e.g. winter barley, wheat or rye). However, winter barley is often grown in tight rotations with limited herbicide diversity, which increases the selection pressure for resistance. The risk of resistance may be slightly higher in winter barley than in cereals such as oats or rye, which are less frequently treated with diflufenican or have a different herbicide regime.

The potential for resistance to diflufenican in winter barley is not inherently higher than in other winter cereals. However, cropping systems and herbicide management practices used in winter barley often increase the risk. Resistance management strategies, including diverse herbicide use and integrated weed control, are crucial regardless of the cereal crop.

ZRMs approved the proposed label provision about strategies to minimize the risk of occurrence and the development of weed resistance against diflufenican. Those, strategy is still valid for winter barley and not require any changes.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

EPPO 1/226 indicates that typically at least 8 specific crop safety trials per major crop are required, to cover the range of conditions of use, including soil types and weather conditions that are likely to be encountered. Research should be conducted in the Poland or/and in other countries from the North-East EPPO zone or neighbouring countries not belonging to the zone. According to the Polish guidelines for well-known active substance should be submitted at least 4-5 phytotoxicity studies performed in two growing seasons on 3-4 varieties. Also, Applicant can use CIRCA for the assessment, but into account must be taken issues related to data protection. Alternatively, Applicant can use the data from the records of other / neighbouring countries – but the justification for using this part by Applicant must be submitted.

The applicant has submitted 10 selectivity trials from North-East EPPO zone (PL) carried out on winter wheat (4 trials), winter rye (3 trials) and winter triticale (3 trials). In the opinion of Evaluator, the Applicant submitted enough phytotoxicity trials for winter wheat at early post-emergence use. For other cereals: winter rye and winter triticale selectivity trials can be extrapolated, especially when the Applicant presented an appropriate number of confirmatory tests (3 for each use) for rye and triticale at early post-emergence use.

Selectivity studies on herbicide were performed in total in 10 trials by companies authorized to conduct studies on efficacy of plant protection products. The trials were performed with the use of different agricultural practice. The trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. The herbicide has been used in two doses: N and 2N. In all trials studied product was compared to the standard reference containing the same active ingredient. Statistical analysis of the data was performed. Also, phytotoxicity effect was assessed during efficacy trials. **No phytotoxicity symptoms caused by DiFlufenikan 500 SC at the proposed dose rate of 0.3 L/ha were recorded in all trials. 2N rate of 0.6 L/ha of the product also did not cause phytotoxicity.**

Evaluation of extending registration to winter barley:

Applicant submitted 4 additional selectivity trials carried out in Poland (N-E EPPO zone) on winter barley in 2022. During those trials dose N (0.3 L/ha) and 2N (0.6 L/ha) was studied in line to appropriate EPPO standard. Hukkata 500 SC at dose N (0.3 L/ha) and 2N (0.6 L/ha) was used as a st. ref. product. Following varieties of winter barley: Carmina, KWS Faro and KWS Meridan (2 trials) were studied during those trials. The appropriate experimental design was applied. Statistical analysis of the data was performed. Also, phytotoxicity effect was assessed during 2 efficacy trials assessed at previous registration.

No phytotoxicity symptoms caused by Danubis (product code: DiFlufenikan 500 SC) at the proposed dose

rate of 0.3 L/ha were recorded in all trials. 2N rate of 0.6 L/ha of the product also did not cause phytotoxicity.

In accordance with the polish harmonization meetings – no efficacy trials are required for the extrapolation of results from winter cereals to winter barley. Only 3-4 selectivity trials carried out on winter barley are needed. Applicant properly presented 4 valid selectivity trials carried out in PL on winter barley, so possibility of the extension of registration on winter barley is accepted by ZRMs.

Effect on the yield of treated plants or plant product

The effect of the test product on winter cereals yield was assessed in ten selectivity trials carried out in the North-East EPPO zone (PL) on winter wheat (4 trials), winter rye (3 trials) and winter triticale (3 trials) as well as winter barley (4 trials). Dose N and 2N was studied during selectivity trials. Submitted trials are sufficient. The evaluation was carried out in accordance with EPPO guidelines. No negative effect on the winter cereals grain yield was observed. Detailed results are presented in each report from selectivity trials. **‘Diflufenikan 500 SC’ can be consider as safe for winter cereals crops on the basis on the submitted documentation by Applicant.**

Evaluation of extending registration to winter barley:

The effects of the test product on winter barley yield was assessed in four selectivity trials carried out in the N-E EPPO zone (PL). Dose N and 2N was studied during selectivity trials. Submitted trials are sufficient. The evaluation was carried out in accordance with EPPO guidelines. No negative effect on winter barley grain yield was observed. Detailed results are presented in each report from selectivity trials. Danubis can be considered as safe for winter cereals (wheat, triticale and rye- previous assessed and winter barley- assessed now) crops on the basis on the submitted documentation by Applicant.

Effects on the quality of plants or plant products

The evaluation was carried out in accordance with EPPO guidelines. Parameters such as grain yield, the weight of thousand grain, moisture content of grain was assessed during 14 trials. Quality of yield of winter cereals in recommended dose of tested product – ‘Diflufenikan 500 SC’ were similar to objects, which used standard reference product. Detailed results are presented in each report from selectivity trials. **Diflufenikan 500 SC’ can be consider as safe for winter cereals (winter wheat, winter triticale and winter rye as well as winter barley) crops on the basis on the submitted documentation by Applicant.**

Evaluation of extending registration to winter barley:

The effect of the test product on winter barley quality of yield was assessed in four selectivity trials carried out in the N-E EPPO zone (PL). Dose N and 2N was studied during selectivity trials. Submitted trials are sufficient. The evaluation was carried out in accordance with EPPO guidelines. No negative effect on the winter barley quality of yield was observed. Detailed results are presented in each report from selectivity trials. Danubis can be considered as safe for winter cereals (wheat, triticale and rye – previous assessed and winter barley- assessed now) crops on the basis on the submitted documentation by Applicant.

Effect on transformation processes

No data were presented to address the risk to transformation processes in accordance with EPPO 243 Effects of plant protection products on transformation processes. Considering that product is applied at early stage (up to BBCH 29 for winter cereals) of the crop, before inflorescence emergence and heading, and as the active ingredients (diflufenican) are not systemic it could be agreed that no negative impact on processing is expected.

Evaluation of extending registration to winter barley: Previous assessment is still valid.

Impact on treated plants or plant products to be used for propagations

EPPO PP1/135 (3) indicates that data are needed for foliar applied herbicides where application is made at or after seed initiation e.g., for cereals when the first node is detectable or where detectable residues

occur in harvested seed. The proposed latest time of application is up to BBCH 29 for winter cereals, which for cereals is after seed initiation. Special trials to investigate this purpose or reasoned case were not submitted. Therefore, either restrictions/warnings based on absence of data or conclusions from other similar diflufenican products out of protection should be implemented.

Evaluation of extending registration to winter barley: Previous assessment is still valid.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops

The evaluation of any possible effects on rotational (succeeding) or replacement crops was not carried out according to the stepwise approach in EPPO PP 1/207 'Effects on succeeding crops'. To examine whether the active substance of – Diflufenican 500 SC can cause negative effects on crops grown after cereals treated with the product a bioassay on representative crops should be conducted.

Half decomposition in soil (DT₅₀): *laboratory tests* – 44.3-237.9 days; *field tests* 224-621 days.

The Applicant proposed provisions for the effect on succeeding plants. it is in line with the provisions found on labels of plant protection products containing diflufenican as an active substance. Diflufenican is used in 80 PPP registered in PL, so its effect on succeeding crops is known. ZRMs accepted that: *“The product decomposes over the growing season without making any damage to succeeding plants. In case of the need to sift the treated plantation, do not grow beetroots, oilseed rape, oats, onions and brassica-cabbage. Other crops can be grown after the performance of ploughing (at least 20cm depth).”*

Evaluation of extending registration to winter barley: Previous assessment is still valid.

Impact on other plants including adjacent crops

An application of Diflufenican 500 SC in respect of the GAP should not present an unacceptable risk for non-target terrestrial plants when risk mitigation measures are considered. Generally, the product is a foliar herbicide effective on broadleaved weeds. Therefore, warnings to avoid spray drift on adjacent crops should appear on the label.

No negative impact on adjacent crops is expected when 5 m no spray buffer zone is maintained. Nevertheless, Diflufenican 500 EC is an herbicide that provides both contact and residual control with residual activity lasting for up to 8 weeks under favourable growing conditions. Therefore, standard warning to avoid spray drift to neighbouring crops and fields should appear on the label.

Evaluation of extending registration to winter barley: Previous assessment is still valid.

Effects on beneficial and other non-target organisms

Products which are containing diflufenican, has been used for many years (substance is known from 1985), not only Poland but also in other European countries. According to current knowledge, Diflufenican 500 SC does not pose any unacceptable risk to other plants also there was no adverse impact on beneficial organisms.

Evaluation of extending registration to winter barley: Previous assessment is still valid.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for determination of diflufenican in Diflufenikan 500 SC was not evaluated as part of the EU review of diflufenican. Therefore, all relevant data are provided and are considered adequate.

The method for determination of diflufenican in Diflufenikan 500 SC formulation is based on high performance liquid chromatography (HPLC) with a UV-VIS DAD detector and external standard. In order to confirm method specificity, chromatograms of acetonitrile, placebo, standard and analysed sample were superimposed and compared.

There were no peaks interfering with the diflufenican peak. The correlation coefficient was $R^2 = 0.999$ (the criterion of acceptability is $R^2 \geq 0.99$). The relative standard deviation of instrument precision for the determined active substance was $H_r = 0.08$ (criterion of acceptability is $H_r \leq 1$). Acceptable relative standard deviation of repeatability for the determined active substance is $\leq 1.53\%$. The obtained results of 0.12% is acceptable. The accuracy of active ingredient determination was estimated by the recovery measurement. The recovery value for the main component should be 97% ÷ 103%. The obtained result 100% is acceptable.

The method for determination of diflufenican in Diflufenikan 500 SC fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure appropriate active substance determination in the formulation.

A CIPAC method exists for the analysis of diflufenican in formulations.

3.4.2 Analytical methods for residues

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

Noticed data gaps (minor) are:

- ILV method for drinking water,
- methods for the analysis of body fluids and tissues.

These data gaps can be covered after authorisation within 2 years.

Commodity/crop	Supported/ Not supported
Winter wheat, triticale	Supported
Winter barley	Supported
Rye	Supported

Adequate analytical methods are available to monitor all compounds given in the respective residue definitions of diflufenican in winter barley have been evaluated and accepted during the first authorisation issuing (see document “diflufenican_fRR Part B5_Danubis 500 SC_Pestila_ProAgri_PL_04.2024”).

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

No acute toxicity studies were performed for Diflufenikan 500 SC. The classification of Diflufenikan 500 SC was based on the composition of the product and was performed according to the Regulation (EC) of the European Parliament and of the Council No. 1272/2008 of December 16th, 2008 *on classification, labelling and packaging of substances and mixtures*. Details on composition and classification of formulations are provided in dRR Part C.

Diflufenikan 500 SC, containing 500 g/L diflufenican does not show toxicity in respect to oral, dermal and inhalation toxicity. Product has no sensitizing properties, and it is not irritating to skin nor to eyes.

Adequate models and calculations are available in the respective toxicity (operator exposure, worker exposure, bystander and resident exposure) of Diflufenikan 500 SC in winter barley have been evaluated and accepted during the first authorisation issuing (see document “diflufenican_fRR Part B6_Danubis 500 SC_Pestila_ProAgri_PL_05.2024”).

3.5.2 Operator exposure

Operator exposure to Di flufenikan 500 SC was not evaluated as part of the EU review of diflufenican. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The operator exposure was assessed against the AOEL agreed in the EU review of diflufenican. No studies were available to determine the dermal absorption, default values as defined in the EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption) and SAN-TE/2018/10591 rev.1 of 24 October 2018 were used for the calculations.

Operator exposure calculations were performed using the EFSA model AOEM (*Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015)*).

According to the model calculations, it can be concluded that the risk for the operator using Di flufenikan 500 SC on intended uses presented in GAP table is acceptable even if operator is not equipped with work wear (arms, body and legs covered) and protective gloves during mixing/loading and during application. However, it is recommended to use workwear (arms, body and legs covered) and protective gloves during mixing/loading and during application.

3.5.3 Worker exposure

Worker exposure to Di flufenikan 500 SC was not evaluated as part of the EU review of diflufenican. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The worker exposure was assessed against the AOEL agreed in the EU review of diflufenican. No studies were available to determine the dermal absorption, default values as defined in the EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption) and SAN-TE/2018/10591 rev.1 of 24 October 2018 were used for the calculations.

Worker exposure calculations were performed using the EFSA model AOEM (*Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015)*) and EUROPOEM II re-entry model (*Hemmen et al (2002) Post-application exposure of workers to pesticides in agriculture, Report of the re-entry working group. EUROPOEM II project. FAIR3 CT96-1406)*).

The results of the exposure estimations show that the use of Di flufenikan 500 SC according to the list of intended uses presented in GAP Table, causes no health risk for the worker even if the workwear (arms, body and legs covered) and gloves are not used. The calculated exposure level to diflufenican is lower than the value of AOEL for this active substance.

Taking into account hygienic rules, it is recommended that a worker inspecting treated area was dressed properly (long trousers, long-sleeve shirt) and equipped with protective gloves.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.5.4 Bystander and resident exposure

Bystander and resident exposure to Di flufenikan 500 SC was not evaluated as part of the EU review of diflufenican. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The bystander and resident exposure was assessed against the AOEL agreed in the EU review of diflufenican. No studies were available to determine the dermal absorption, default values as defined in the EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption) and SANTE/2018/10591 rev.1 of 24 October 2018 were used for the calculations.

Bystander and resident exposure calculations were performed using the EFSA model AOEM (*Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015)*).

The reference value acutely toxic active substance (RVAAS) for diflufenican is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards this active substance.

The results of the exposure estimations show that all estimated values are below the systemic AOEL for diflufenican. It can be concluded that the exposure of bystander and resident (children and adult) to diflufenican contained in the formulation Diflufenikan 500 SC causes no risk to human health if the product is used in accordance with the intended uses listed in the GAP Table.

Buffer zone 2-3m.

3.6 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 0.02 mg/kg for diflufenican in wheat (incl. triticale), barley and rye as laid down in Reg. (EU) 396/2005 (last amendment - Reg. (EU) 2017/623) is not expected.

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

Adequate data are available to level of residues and consumer exposure of diflufenican in winter barley, have been evaluated and accepted during the first authorisation issuing (see document “diflufenican_fRR Part B7_Danubis 500 SC_Pestila_ProAgri_PL_corr.06.2024”).

3.6.1 Residues

Stability of Residues

Freezer storage stability study indicated that residues of diflufenican are stable for up to 24 months in wheat forage, wheat grain and wheat straw. These data are sufficient to cover the trials on cereals supporting the intended GAP for Diflufenikan 500 SC.

Metabolism in plants and animals

Presented data are acceptable. No additional studies are required.

Plant and animal residue definitions for monitoring and risk assessment Diflufenican (EFSA, 2013; Regulation (EU) 2017/623).

Magnitude of residues in plants

Proposed GAP:

Winter wheat, Winter barley, Winter triticale, Winter Rye: 1 application; BBCH 10-29, 100 - 150 g sa/ha

No new data are submitted in the framework of this application. Applicant refers to the unprotected EU data.

cGAP from DAR, 2006:

1 x 0.19 kg as/ha, BBCH: 25-33, PHI n.r.

1 x 0.15 kg as/ha, BBCH: 29-31, PHI n.r.

E/RA: 21 x <0.01, 5x <0.02 mg/kg

Sufficient data are available to support the proposed uses. According to the SANTE/2019/12752 Rev01 extrapolation from barley and wheat to rye and triticale is possible before forming of the edible part.

The residues arising from the proposed uses will not exceed the MRLs established for wheat, barley, triticale and rye (Reg. (EU) 2017/623)

All proposed uses are accepted.

Livestock feeding studies

The new mode of calculation modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

Magnitude of residues in processed commodities

No new data submitted in the framework of this application. As residues of diflufenican exceeding 0.1 mg/kg are not expected in the treated crops and since the chronic exposure does not exceed 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Rotational study

Considering available data, no study dealing with magnitude of residues in succeeding crops is needed. Risk mitigation measures in case of earlier liquidation of the plantation can be applied at national level.

According to the EFSA, waiting period of 150 days before planting root crops seems the most appropriate.

Other / special studies

Cereals have not melliferous capacity. No further data is required.

Estimation of exposure through diet and other means

The proposed uses of diflufenican in the formulation Diflufenikan 500 SC does not represent unacceptable chronic risks for the consumer.

3.6.2 Consumer exposure

Consumer exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1; calculation version 06/01/2021) provided on the internet homepage of EFSA (<https://www.efsa.europa.eu/>). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

As ARfD for diflufenican was not deemed necessary, acute risk assessment is not relevant.

ADI	0.2 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	0.7% (based on NL toddler diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not relevant. TMDI < 100%.
ARfD	ARfD was not deemed necessary.

IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	Not relevant. ARfD was not deemed necessary.
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The proposed uses of diflufenican in the formulation Diflufenikan 500 SC does not represent unacceptable chronic risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PECs modelling for diflufenican and its metabolites AE B107137 and AE 0542291 was performed with Excel calculator based on simple equations included in FOCUS soil persistence document issued in 1997. PECs for formulation was obtained from PECs for diflufenican (worst case) taking into account content of active substance and density of the formulation. The worst case PECs were used in further risk assessment.

ZRMS Accepted.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} for diflufenican and its metabolites AE B107137 and AE 0542291 after application to winter cereals (included winter barley) were calculated with PELMO 6.6.4 and PEARL 5.5.5.

For all scenarios important to Poland (Châteaudun, Hamburg, Kremsmünster)

PEC_{gw} values for diflufenican and its metabolites are below the trigger value of 0.1 µg/L.

ZRMS Accepted.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

PEC_{sw} for diflufenican and its metabolites after application to winter cereals (included winter barley) were calculated with FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v.5.0.1. For all scenarios important to Poland (D3, D4, R1) calculations was presented. PEC_{sw} values were used in aquatic risk assessment.

ZRMS Accepted.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The fate and behaviour of diflufenican in air was evaluated during the EU review. In accordance with EFSA Scientific Report (2007) 122, 1-84, diflufenican has a vapour pressure of $4.25 \cdot 10^{-6}$ Pa at 25 °C and a Henry's Law constant of $> 1.18 \cdot 10^{-2}$ Pa·m³/mol at 20 °C and could be considered slightly volatile. Volatilization of diflufenican from plant surface and soil was negligible (plants: 0.3 AR % after 24 h, soil: 0.0 – 0.005% AR after 24 h). A theoretical calculation of the potential for photo-oxidation resulted in a half-life of 3.3 d based on an OH radical concentration of $1.5 \cdot 10^6$ cm⁻³ on a 12h day basis. Based on the negligible potential for volatilization from plant and soil surface it is considered that exposure to air and therefore long range transport through air is insignificant for diflufenican. However, during expert's meeting soil anaerobic metabolite 2,4-difluoroaniline was found to be very volatile and may need to be assessed for the air compartment and for transport through air when prolonged anaerobic conditions are expected to occur in soil. The meeting agreed that at any case exposure is expected to be "very low".

ZRMS Accepted.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

Effects on birds for Di flufenikan 500 SC were not evaluated as part of the EU review of di flufenikan. However further data on Di flufenikan 500 SC is not relevant as data for each active substance on toxicity to birds are considered essential. It is possible to extrapolate from data for each active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for Di flufenikan 500 SC with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of Di flufenikan 500 SC to birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substances, as well as SV_{90} and SV_m .

Drinking water exposure (leaf scenario) has not been estimated since Di flufenikan 500 SC is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures. Drinking water exposure (puddle scenario) has not been performed since the ratio of effective application rate to relevant endpoint does not exceed 50 ($Koc < 500 \text{ L/kg}$).

Exposure for earthworm-eating birds and fish-eating birds via secondary poisoning has also been estimated since $\log P_{ow}$ of di flufenikan is above the trigger value of 3.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to birds from the proposed use of Di flufenikan 500 SC. No risk management measures are required.

The existing risk assessment for birds fully covers the risk arising from label extension (winter barley). No further risk assessment for birds is needed. According to the existing risk assessment, it can be concluded that no unacceptable risk for birds from the proposed additional use in winter barley is expected. No risk management measures are required.

ZRMS Accepted.

Terrestrial vertebrates (other than birds)

Effects on mammals for Di flufenikan 500 SC were not evaluated as part of the EU review of di flufenikan. However further data on Di flufenikan 500 SC is not relevant as data for each active substance on toxicity to mammals are considered essential. It is possible to extrapolate from data for each active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for Di flufenikan 500 SC with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on terrestrial vertebrates other than birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of Di flufenikan 500 SC to terrestrial vertebrates other than birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with di flufenikan, as well as SV_{90} and SV_m .

Drinking water exposure (puddle scenario) has not been performed since the ratio of effective application rate to relevant endpoint does not exceed 50 ($Koc < 500 \text{ L/kg}$).

Exposure for earthworm-eating mammals and fish-eating mammals via secondary poisoning has also been estimated since $\log P_{ow}$ of diflufenikan is above the trigger value of 3.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to mammals from the proposed use. No risk management measures are required.

The existing risk assessment for mammals covers the drinking water risk arising from label extension (winter barley). In case of spray exposure, additional risk assessment has been performed resulting in acute and long-term TER values below the triggers of 10 and 5, respectively. According to the risk assessment, it can be concluded that no unacceptable risk for mammals from the proposed additional use in winter barley is expected.

ZRMS Accepted.

3.8.2 Effects on aquatic species

Effects on aquatic organisms for Diflufenikan 500 SC were not evaluated as part of the EU review of diflufenikan. The studies on effects of Diflufenikan 500 SC on algae, Daphnia and aquatic plants were submitted in this dossier and deemed acceptable for evaluation and authorisation of Diflufenikan 500 SC.

Risk assessments for Diflufenikan 500 SC with the proposed use pattern was carried out according to the latest guidance for risk assessment for aquatic organisms in edge-of-field surface water EFSA Journal 2013; 11(7):3290.

PEC/RAC values were calculated on the basis of PEC_{sw} calculations as well as worst case toxicity end-points from studies for active substance/reference formulation, metabolites and formulation Diflufenikan 500 SC. PEC_{sw} Step 3/RAC values for active substance were less than 1 for few scenarios including scenarios relevant for Poland so further evaluation with Step 4 PEC_{sw} was performed.

For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that Diflufenikan 500 SC used according to proposed GAP does not pose unacceptable risk to aquatic organisms provided 5m vegetated buffer zone is applied.

Classification of Diflufenikan 500 SC was done on the basis of formulation Diflufenikan 500 SC studies' results as well as active substance and co-formulants properties. The proposed classification of the product Diflufenikan 500 SC is:

Aquatic Acute 1, H400

Aquatic Chronic 1, H410

In case of label extension (winter barley), PEC/RAC values for active substance were calculated with Step 3 and Step 4 PEC_{sw} values for all available scenarios. PEC/RAC values for metabolites were calculated with Step 1 PEC_{sw} values.

The PEC/RAC values for scenarios relevant for Polish conditions are below the trigger value of 1 for winter barley, indicating the acute and the long risk assessment for aquatic is acceptable when below listed risk mitigations are applied:

- winter barley: 5 m vegetated buffer zone to surface water bodies is required when conventional spraying techniques are applied.

ZRMS Accepted.

Based on PEC/RAC calculations, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses for Diiflufenikan 500 SC, provided that following risk mitigation measures are taken into account:

- a vegetative buffer strip of 5 m to surface water bodies is required when conventional spraying techniques are applied.

3.8.3 Effects on bees

The risk assessment for adult bees based on the laboratory tests with diiflufenikan and the formulation Diiflufenikan 500 SC are considered acceptable.

All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field.

The chronic toxicity test for adult bees and the chronic test for larvae have been provided for authorisation of plant protection product Diiflufenikan 500 SC. The studies have been accepted by zRMS.

The risk assessment for bees based on GD for bees, 2013 (however is still not implemented at EU level) is accepted by RMS. The screening step risk assessment above has indicated no unacceptable acute risk for honeybees and bumblebees.

The existing risk assessment for bees fully covers the risk arising from label extension (winter barley). No further risk assessment for bees is needed. According to the existing risk assessment, it can be concluded that no unacceptable risk for bees from the proposed additional use in winter barley is expected. No risk management measures are required.

ZRMS Accepted.

3.8.4 Effects on other arthropod species other than bees

The risk assessment to non-target arthropods based on the laboratory tests with diiflufenikan and the formulation Diiflufenikan 500 SC are considered acceptable.

The HQ values were considerably less than 2. It can be concluded that used at max. application rate of 0.3 L/ha (150 g as/ha) to protect cereals according to proposed GAP, does not pose unacceptable in-field and off-field risk to non-target arthropods. No risk mitigations are required.

The existing risk assessment for arthropods fully covers the in-field and off-field risk arising from label extension (winter barley). According to the existing risk assessment, it can be concluded that no unacceptable risk for arthropods from the proposed additional use in winter barley is expected. No risk management measures are required.

ZRMS Accepted.

3.8.5 Effects on soil organisms

The long-term risks of Diiflufenikan 500 SC to soil meso- and macro-organisms were assessed based on toxicity exposure ratios between toxicity endpoints and maximum PEC_{soil} . The relevant predicted environmental concentrations in soil (PEC_{soil}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate).

Risk assessment for earthworms

Risk for earthworms is low. No additional calculations for earthworms are needed.

ZRMS Accepted.

Risk assessment for macroorganisms other than earthworms

As stated in Commission Regulation EU No 284/2013 of 1 March 2013, “For plant protection products applied as a foliar spray, data on the relevant two non-target arthropod species might be taken into account for a preliminary risk assessment. If effects do occur on either species, testing on *Folsomia candida* and *Hypoaspis aculeifer* shall be required.”

The formulated product Di flufenikan 500 SC is applied as a foliar spray treatment. As demonstrated above, acceptable risks are expected towards the earthworms and a low in-field and off-field risk is demonstrated for non-target arthropods - such as - *Typhlodromus pyri*, *Aphidius rhopalosiphi* (standard laboratory studies) in cereals (0.3 L formulation/ha, equivalent to 150 g di flufenikan/ha). On the other hand, all the long-term TER values are much higher than the trigger value of 5, indicating that Di flufenikan 500 SC poses low acute risk also for earthworms. Therefore, the risk assessment for macroorganisms other than earthworms is not required. In addition, the risk assessment for *Folsomia candida* and *Hypoaspis aculeifer* based on the data from EFSA Scientific Report (2007) 122, 1-84 (however for similar formulation) was performed by Applicant.

All the long-term TER values are much higher than the trigger value of 5, indicating that Di flufenikan 500 SC poses low acute risk to earthworms and macroorganisms other than earthworms (*Folsomia candida*, *Hypoaspis aculeifer*)) when applied according to the proposed use rates (cereals).

The existing risk assessment for earthworms and other non-target soil organisms fully covers the risk arising from label extension (winter barley). No further risk assessment for earthworms and other non-target soil organisms is needed. According to the existing risk assessment, it can be concluded that no unacceptable risk for earthworms and other non-target soil organisms from the proposed additional use is expected. No risk management measures are required.

ZRMS Accepted.

Micro-organisms

The risk of Di flufenikan 500 SC to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for active substance, metabolites and the formulated product Di flufenikan 500 SC with predicted application concentrations (PECs) or application rate for active substance, metabolites and the formulation.

According to the performed risk assessment it was assessed that the application of Di flufenikan 500 does not pose unacceptable risk to soil micro-organisms. No risk management measures are required.

The existing risk assessment for micro-organisms fully covers the risk arising from label extension (winter barley). No further risk assessment for microorganisms is needed. According to the existing risk assessment, it can be concluded that no unacceptable risk for microorganisms from the proposed additional use is expected. No risk management measures are required.

ZRMS Accepted.

3.8.6 Effects on non-target terrestrial plants

Effects on non-target terrestrial plants for Di flufenikan 500 SC were not evaluated as part of the EU review of di flufenikan. The studies on seedling emergence and vegetative vigour for Di flufenikan 500 SC were submitted in this dossier and deemed acceptable for evaluation and authorisation of Di flufenikan 500 SC.

The risk of Di flufenikan 500 SC to non-target plants was assessed from toxicity exposure ratios between toxicity endpoints for the formulation Di flufenikan 500 SC and off-field predicted environmental rate.

Based on the predicted rates of Diflufenikan 500 SC in off-field areas, the TER values describing the risk for non-target plants following exposure to Diflufenikan 500 SC according to the GAP of the formulation Diflufenikan 500 SC achieve the acceptability criteria $TER \geq 5$, with applying:

- **5 m without use of drift reducing nozzles**

To protect non-target plants respect an unsprayed buffer zone of 5m to non-agriculture area.

The existing risk assessment for non-target plants fully covers the risk arising from label extension (winter barley). The TER values describing the risk for non-target plants following exposure to Diflufenikan 500 SC according to the GAP of the formulation Diflufenikan 500 SC achieve the acceptability criteria $TER \geq 5$, with applying:

- **5 m without use of drift reducing nozzles. ZRMS Accepted.**

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

All metabolites are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B8). Assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Diflufenikan 500 SC contains diflufenican which is approved as a candidate for substitution because two of PBT. As a conclusion of the comparative assessment plant protection product Diflufenikan 500 SC should be authorised.

Based on the comparative assessment it can be concluded that use 1 from GAP table in 2.6 is not suitable for substitution because there is no evident benefit resulted from the conducted assessment. Substitution should be restricted to cases in which the benefit is evident (SANCO/11507/2013 Guidance). Moreover, possible alternatives do not show significantly lower risk to neither health nor the environment.

For more details, please refer to Comparative Assessment document.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

2 years ambient shelf life study results.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Sekcja skuteczność: ~~Wprowadzone zmiany w liście zaakceptowanych chwastów oraz identyfikacji ich wrażliwości. Dodano do etykiety żyto ozime i pszenżyto ozime (zaakceptowane w G.A.P.). Jęczmień ozimy został wykreślony z etykiety z uwagi na brak badań selektywności umożliwiające ekstrapolację wyników z innych zboż ozimych. Nie zmieniano pozostałych zapisów.~~ **Zaakceptowano rozszerzenie rejestracji na jęczmień ozimy.** Zapisów etykiety – nie zmieniono.

Sekcja pozostałości: Wprowadzono zmianę dotyczącą upraw następczych.

Sekcja fizykochemii: ~~brak uwag~~ Ponieważ po przechowywaniu środka przez 2 lata w temp. otoczenia nastąpiło rozdzielanie faz (ok. 2% v/v) w etykiecie powinien znajdować się zwrot „Środek przed użyciem dokładnie wymieszać”. Zwrot taki jest już umieszczony w sekcji „SPORZĄDZANIE CIECZY UŻYTKOWEJ”.

Sekcja losu i zachowania w środowisku: ~~brak uwag~~ **Zaakceptowano rozszerzenie rejestracji na jęczmień ozimy.** Zapisów etykiety – nie zmieniono.

Ekotoksykologia: W celu ochrony roślin konieczne jest wyznaczenie strefy ochronnej o szerokości: 5 m od terenów nieużytkowanych rolniczo. W celu ochrony organizmów wodnych konieczne jest wyznaczenie od zbiorników i cieków wodnych zadarnionej strefy ochronnej o szerokości 5 m. **Zaakceptowano rozszerzenie rejestracji na jęczmień ozimy.** Zapisów etykiety – nie zmieniono.

Posiadacz zezwolenia:

Pestila Sp. z o. o., Studzianki 24a, 97-320 Wolbórz, tel./fax: +48 44 616 43 75,
e-mail: info@pestila.pl.

Danubis 500 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

Diflufenikan (substancja z grupy fenoksynikotynoanilidów) - **500 g/l** (41,9 %)

Zezwolenie MRiRW nr R - **XX/RRRR z dnia DD.MM.RRRR r.**



Niebezpieczeństwo

- H410 – Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208 – Zawiera 1,2-benzoizotiazol-3(2H)-on. Może powodować wystąpienie reakcji alergicznej.
EUH 401 – W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P280 – Stosować ochronę oczu, rękawice i odzież roboczą
P391 – Zebrać wyciek.

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu kontaktowym, stosowany nalistnie oraz dogłębowo, w formie stężonej zawiesiny do rozcieńczania wodą (SC) przeznaczony do jesiennego zwalczania chwastów.

Zgodnie z klasyfikacją HRAC substancja czynna diflufenikan zaliczana jest do grupy 12 (dawnej grupy F1).

DZIAŁANIE NA CHWASTY

Środek pobierany głównie przez liście chwastów, oraz w mniejszym stopniu przez korzenie.

Wrażliwe chwasty kielkują, ale po kontakcie z środkiem pojawiają się na nich odbarwienia pod postacią białych, żółtych i/bądź różowych plam, które następnie powiększają się. Następstwem odbarwień jest zamieranie chwastów. Najlepszy efekt chwastobójczy można uzyskać poprzez stosowanie środka gdy chwasty znajdują się we wczesnych fazach rozwojowych, podczas ich kielkowania bądź krótko po ich wschodach, gdy znajdują się w fazie siewki.

Optymalna wilgotność gleby sprzyja działaniu środka Danubis 500 SC.

Dawka 0,2 l/ha

Chwasty wrażliwe	tasznik pospolity, fiołek polny, przetacznik perski
Chwasty średniowrażliwe	miotła zbożowa, bodziszek drobny, gwiazdnica pospolita, jasnota purpurowa
Chwasty średnioodporne	chaber bławatek
Chwasty odporne	rumianek pospolity

Dawka 0,3 l/ha

Chwasty wrażliwe	tasznik pospolity, chaber bławatek, jasnota purpurowa, gwiazdnica pospolita, fiołek polny, przetacznik perski
Chwasty średniowrażliwe	miotła zbożowa, rumianek pospolity, bodziszek drobny

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

Pszenica ozima, jęczmień ozimy pszenżyto ozime, żyto ozime.

Maksymalna dawka dla jednorazowego zastosowania: 0,3 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,2-0,3 l/ha.

Termin stosowania środka: stosować jesienią, bezpośrednio po siewie zbóż do końca fazy krzewienia (BBCH 00-29).

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

ŚRODKI OSTROŻNO ŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecany terminie zapewniającym optymalne zwalczanie chwastów,
- dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
- stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
- używać kwalifikowanego materiału siewnego,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Środka nie stosować:

- w zbożach z wsiewką roślin motylkowatych,
- na rośliny osłabione lub uszkodzone przez choroby, szkodniki, przymrozki lub suszę.
- w temperaturze powietrza poniżej 8°C

3. Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

OKRESY KARENCJI

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie wymagany

NASTĘPSTWO ROŚLIN

Środek rozkłada się w glebie w ciągu okresu wegetacji nie stwarzając zagrożenia dla roślin uprawianych następczo.

W przypadku konieczności wcześniej likwidacji plantacji na której środek został zastosowany (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki), nie uprawiać roślin korzeniowych, rzepaku, owsa, roślin kapustnych, warzyw cebulowych oraz, w przypadku gleb lekkich, grochu. Po wykonaniu orki na głębokość minimum 20 cm, można uprawiać pozostałe rośliny.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne (nitrylowe, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Podczas oprysku należy stosować strefę ochronną w odległości co najmniej 5 m od budynków mieszkalnych/siedlisk oraz osób postronnych.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres przewencji):
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie od zbiorników i cieków wodnych zadarnionej strefy ochronnej o szerokości 5 m.

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA ORAZ PIERWSZA POMOC

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku połknięcia: W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc lub z lekarzem.

W przypadku dostania się na skórę: umyć dużą ilością wody z mydłem.

W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Zawartością opakowania przed użyciem wstrząsnąć. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszałem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości.

Po wleńiu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.

W przypadku stosowania środka w mieszaninie z innymi środkami przestrzegać ściśle zaleceń dotyczących sporządzania cieczy użytkowej tych środków.

W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy należy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Letter of Access is provided in a separate appendix.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Section B1-B2 and B4: Identity, Physical and Chemical Properties, Further information							
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Kupiec J.	2022	DIFLUFENIKAN 500 SC. Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Report No BF – 24/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Published: no	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 2.2.1	Ołowski G.	2022	DIFLUFENIKAN 500 SC. Determination of explosive properties. Report No BW-15/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Published: no	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 2.2.2	Flasińska P.	2022	Diflufenikan 500 SC.Determination of flash point, auto-ignition	N	Y	New data for formulation, not	Pestila*

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.3.1 KCP 2.3.3			temperature and oxidizing properties. Report No BC -44/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Published: no			previously submitted or evaluated. Study conducted in compliance with GLP.	ProAgri**
KCP 2.7.5	Rymarzak O.	2024	Final report, DIFLUFENIKAN 500 SC, Determination of physicochemical properties Report No BF – 24/22 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry GLP Yes Not published	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*
Section B3: Efficacy Data and Information							
KCP 3.2/01	Kukuła A.	2021	Efficacy of H-01-2020 for the control of weeds in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0821-1 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/02	Kukuła A.	2021	Efficacy of H-01-2020 for the control of weeds in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0821-2 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/03	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and dicotyledonous weeds in winter wheat. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 001GP202103 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/04	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and di-	N	Y	New data for formulation, not	Pestila*

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			cotyledonous weeds in winter wheat. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 001GP202104 GEP: Yes Published: No			previously submitted or evaluated. Study conducted in compliance with GEP.	ProAgri**
KCP 3.2/05	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and di-cotyledonous weeds in winter barley. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 002GP202102 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/06	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and di-cotyledonous weeds in winter barley. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 002GP202103 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/07	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and di-cotyledonous weeds in winter triticales. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 003GP202102 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/08	Figurski R.	2022	Efficacy evaluation of H-01-2020 against mono and di-cotyledonous weeds in winter triticales. 2022; Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 003GP202103 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2/09	Szemendera A.	2023	Efficacy of H-01-2020 in weed control in winter wheat, Poland 2022; Fertico Sp. z o.o., Poland; Report No.: 347_01_F22_060 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/01	Kukuła A.	2021	Selectivity of H-01-2020 in winter wheat. 2021; AGRECO Sp. z o.o., Poland; Report No.: 21PRO0822-1 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/02	Kukuła A.	2022	Selectivity of H-01-2020 in winter wheat. 2022; AGRECO Sp. z o.o., Poland; Report No.: 22PRO0974-3 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/03	Kukuła A.	2022	Selectivity of H-01-2020 in winter wheat. 2022; AGRECO Sp. z o.o., Poland; Report No.: 22PRO0974-4 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/04	Szemendera A.	2023	Selectivity of H-01-2020 applied in control of weeds in winter wheat, Poland 2022; Fertico Sp. z o.o., Poland; Report No.: 348_01_F22_061 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/05	Figurski R.	2023	Selectivity of H-01-2020 in winter rye. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202201 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/06	Figurski R.	2023	Selectivity of H-01-2020 in winter rye.	N	Y	New data for formulation, not	Pestila*

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202202 GEP: Yes Published: No			previously submitted or evaluated. Study conducted in compliance with GEP.	ProAgri**
KCP 3.4/07	Figurski R.	2023	Selectivity of H-01-2020 in winter rye. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202203 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/08	Figurski R.	2023	Selectivity of H-01-2020 in winter triticales. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202204 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/09	Figurski R.	2023	Selectivity of H-01-2020 in winter triticales. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202205 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/10	Figurski R.	2023	Selectivity of H-01-2020 in winter triticales. Green & Property Consulting Anna Huszcza-Podgórska. Poland; Report No.: 06GPAS202206 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/11	Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-3 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.4/12	Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-4 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/13	Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-1 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.4/14	Kukuła A.	2022	Selectivity of H-01-2020 in winter barley AGRECO Sp. z o.o., Poland; Report No.: 22PRO0975-2 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
Section B5: Analytical Methods							
KCP 5.1.1	Kupiec J.	2022	DIFLUFENIKAN 500 SC. Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Report No BF – 24/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Published: no	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*
KCP 5.1.2/01 filled as KCP 10.3.1.1.1/02	Kulec-Płoszczyca E.	2022	Diflufenikan 500 SC Bumblebees (<i>Bombus</i> spp.), Acute Oral Toxicity Test Study code: B-100-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*
KCP 5.1.2/02 filled as KCP 10.3.1.1.2/02	Kulec-Płoszczyca E.	2022	Diflufenikan 500 SC Bumblebees (<i>Bombus</i> spp.), Acute Contact Toxicity Test Study code: B-102-22	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila* ProAgri*

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished			with GLP.	
KCP 5.1.2/03 (filed as KCP 10.2.1.3/02)	Czarnecka M.	2022	Diflufenikan 500 SC Water-sediment <i>Myriophyllum spicatum</i> toxicity test Study code: W-06-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*
KCP 5.1.2/04 (filed as KCP 10.2.1.3/01)	Czarnecka M.	2022	Diflufenikan 500 SC <i>Daphnia magna</i> , Acute Immobilisation Test Study code: W-07-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*
KCP 5.1.2/05 (filed as KCP 10.2.1.3/01)	Czarnecka M.	2022	Diflufenikan 500 SC <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>), Growth inhibition test Study code: W-08-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*
KCP 5.1.2/06 (filed as KCP 10.2.1.4/01)	Czarnecka M.	2022	Diflufenikan 500 SC <i>Lemna gibba</i> CPCC 310, Growth inhibition test Study code: W-09-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*
KCP 5.1.2/07 (filed as KCP 10.4.1.1/01)	Pieczka P.	2022	Diflufenikan 500 SC Earthworm reproduction test (<i>Eisenia andrei</i>) Study code: G-89-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/08 (filed as KCP 10.6.2/02)	Pieczka P.	2022	Unpublished Diflufenikan 500 SC Terrestrial Plant Test: Vegetative Vigour Test Study code: G-91-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri*
Section B8: Environmental Fate							
KCP 9.2.4/01	Hara-Skrzypiec A.	2022	Diflufenikan 500 SC Calculation of predicted environmental concentrations of diflufenikan and its metabolites in groundwater using the FOCUS groundwater scenarios (FOCUS PEARL, FOCUS PELMO) Company Report No: EST/22/2022 ESTICON Sp. z o.o. GLP: No Published: No	N	N	Not relevant	Pestila* ProAgri**
KCP 9.2.5/01	Hara-Skrzypiec A.	2022	Diflufenikan 500 SC Calculation of Predicted Environmental Concentrations of diflufenikan and its metabolites in surface water using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/21/2022 ESTICON Sp. z o.o. GLP: No Published: No	N	N	Not relevant	Pestila* ProAgri**
Section B9: Ecotoxicology							
KCP 10.2.1.3/01	Czarnecka M	2022	Diflufenikan 500 SC <i>Daphnia magna</i> , Acute Immobilisation Test Study Code: W-07-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.2.1.3/01	Czarnecka M	2022	Diflufenikan 500 SC <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>), Growth inhibition test Study Code: W-08-22	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished			with GLP.	
KCP 10.2.1.4/01	Czarnecka M	2022	Diflufenikan 500 SC <i>Lemna gibba</i> CPCC 310 Growth inhibition test Company Report No: W-09-22 Source: Institute of Industrial Organic Chemistry Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.2.1.3/02	Czarnecka M	2022	Diflufenikan 500 SC Water-sediment <i>Myriophyllum spicatum</i> toxicity test Study Code: W-06-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.3.1.1.1/01	Kulec-Płoszczyca E	2022	Diflufenikan 500 SC Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test Study Code: B-99-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.3.1.1.1/02	Kulec-Płoszczyca E	2022	Diflufenikan 500 SC Bumblebees (<i>Bombus</i> spp.), Acute Oral Toxicity Test Study Code: B-100-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.3.1.1.2/01	Kulec-Płoszczyca E	2022	Diflufenikan 500 SC Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Study Code: B-101-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.3.1.1.2/02	Kulec-Płoszczyca E	2022	Diflufenikan 500 SC Bumblebees (Bombus spp.), Acute Contact Toxicity Test Study Code: B-102-22 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.4.1.1/01	Pieczka P	2022	Diflufenikan 500 SC Earthworm reproduction test Study Code: G-89-21 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.5/01	Pieczka P	2022	Diflufenikan 500 SC Soil Microorganisms: Nitrogen Transformation Test Study Code: G-90-21 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.6.2/01	Pieczka P	2022	Diflufenikan 500 SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study Code: G-92-21 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 10.6.2/02	Pieczka P	2022	Diflufenikan 500 SC Terrestrial Plant Test: Vegetative Vigour Test Study Code: G-91-21 Source: Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**

*Pestila Spółka z ograniczoną odpowiedzialnością (short name: Pestila Sp. z o.o.)

**ProAgri Spółka z ograniczoną odpowiedzialnością or ProAgri International Spółka z ograniczoną odpowiedzialnością (short name: ProAgri Sp. z o.o. or ProAgri International Sp. z o.o.)

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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The following tables are to be completed by MS

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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List of data relied on and not submitted by the applicant but necessary for evaluation

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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