

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: Diflufenikan 500 SC

Product name(s): -

Chemical active substance:

diflufenican, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE 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
09.2023	Change in GAP table
10.2023	ZRMs evaluated dRR submitted by Applicant.
January 2024	The final Registration Report
07.2024	Label extension acc. Art. 33 Reg (EC) 1107/2009 for professional user
February 2025	zRMS assessment of Part B1-2,4 update (2-year stability study)
03.2025	ZRMs assessed the possibility of the extension of authorisation for use on winter barley
07.2025	The final Registration Report

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. This application is according to the Article 33 of Regulation 1107/2009.

In case of active substances data out of protection are used. In addition to the submission of studies as listed in particular sections, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

This is application to extend the authorisation of a plant protection product (PPP) already authorised in Poland to major uses in winter barley not yet covered by that authorisation. This document describes the acceptable use conditions required for extension of the registration of Di flufenikan 500 SC containing 500 g/l diflufenican according to art. 45 of Reg. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland	Danubis 500 SC, authorisation No. R-99/2024

0.1.3 Regulatory history of the active(s)

0.1.3.1 Diflufenican

Table 0.1-2: Summary of regulatory history of CAS No: 83164-33-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2008/66/EC of 30 June 2008 amending Council Directive 91/414/EEC to include bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinochloramine as active substances https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0066&from=EN COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the

Status	
	<p>Council as regards the list of approved active substances https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&from=EN</p> <p>COMMISSION IMPLEMENTING REGULATION (EU) 2019/1589 of 26 September 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanatemethyl, triflusulfuron and tritosulfuron https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1589&from=EN</p> <p>COMMISSION IMPLEMENTING REGULATION (EU) 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1449&from=EN</p> <p>COMMISSION IMPLEMENTING REGULATION (EU) 2022/1480 of 7 September 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofopP-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusulfuron and tritosulfuron https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R1480&from=EN</p> <p>COMMISSION IMPLEMENTING REGULATION (EU) 2023/2592 of 21 November 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the</p>

Status	
	approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, 2-phenylphenol (incl. its salts such as sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fluazifop P, lenacil, napropamide, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, spiroxamine, sulphur, tetraconazole and tri-allate https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L_202302592
RMS	CZ
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2009
Date of first Commission (re-registration) deadline (Step 1)	30/06/2009
Date of final Commission (re-registration) deadline (Step 2)	31/12/2012
Current expiration of approval	15/01/2026
Low risk substance or Candidate for Substitution?	CfS

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

In this overall assessment Member States must pay particular attention to the protection of aquatic organisms and non-target plants.

The SANCO report for Diflufenican (SANCO/3782/08 - rev. 1 – 14 March 2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 17 December 2007.

Table 0.1-3: Information on minimum purity of diflufenican

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
970 g/kg (on a dry weight basis)	minimum purity of active substance – confidential information referred in Part C of dRR Equivalence report available: Y RMS: UK

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

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

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

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Not relevant.	Not relevant.	Not relevant.

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

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

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

Efficacy section: 1 (use on winter barley is also safe)
Residues section: 1
Environmental fate and behavior section: 1 (use on winter barley is also safe)
Ecotoxicology section: 1 (use on winter barley is also safe)

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

Efficacy section: none
Residues section: none
Environmental fate and behavior section: none
Ecotoxicology section: none

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

zRMS main conclusions:

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.~~

Efficacy section:

Diflufenikan 500 SC can be granted in line to accepted GAP table and label project in Poland. **On the basis on submitted documentation (4 additional selectivity trials carried out in Poland on barley) – authorisation of Danubis 500 SC can be extended on winter barley.**

Mammalian toxicology section:

DANUBIS 500 SC is unclassified and Contains 1,2-benzisothiazol-3(2H)-on. May produce an allergic reaction. [EUH208].

Residues section: uses are accepted.

Environmental fate and behaviour section:

No risk for ground water is expected after application of Diflufenikan 500 SC. **Danubis 500 SC can be extended on winter barley**

Ecotoxicology section: Proposed uses are accepted. **Danubis 500 SC can be extended on winter bar-**

ley.

Conclusion:

1. Based on PEC/RAC calculations, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses for Diflufenikan 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.

Appendix 1 ALL intended uses

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

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

Formulation type: SC ^(a, b)
Conc. of as 1: 500 ^(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)	Mem- ber state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests 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		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Mem- ber 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	<u>Susceptible weeds (0.2L/ha):</u> Shepherd's purse <i>Capsella bursa-</i> <i>pastoris</i> CAPBP; Field pansy <i>Viola arvensis</i> VI- OAR; Bird's-eye speedwell VERPE <i>Veronica persica</i> <u>Susceptible weeds (0.3L/ha):</u> Shepherd's purse <i>Capsella bursa-</i> <i>pastoris</i> CAPBP; Cornflower <i>Centaurea cyanus</i> CENCY; Purple deadnettle <i>Lamium pur-</i> <i>pureum</i> LAMPU; Common chickweed <i>Stellaria</i> <i>media</i> STEME; Field pansy <i>Viola arvensis</i> VI- OAR; Bird's-eye speedwell VERPE <i>Veronica persica</i> <u>Moderately susceptible weeds</u> <u>(0.2L/ha):</u> Silky apera <i>Apera spica-venti</i> APESV; Purple deadnettle <i>Lamium pur-</i> <i>pureum</i> LAMPU Common chickweed <i>Stellaria</i> <i>media</i> STEME; Small-flower geranium GERPU <i>Geranium pusillum</i>	broadcast spraying	BBCH 00-29 Autumn applica- tion 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 a) 150g b) 150g	100- 400	N/A	N/A Efficiency section: made changes in the list of susceptible weed spe- cies

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Mem- ber 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		
				<u>Moderately susceptible weeds</u> (0.3L/ha): Silky apera <i>Apera spica-venti</i> APESV; Small-flower geranium GERPU <i>Geranium pusillum</i> Wild chamomile MATCH <i>Matri-</i> <i>caria chamomilla</i> <u>Moderately resistant weeds</u> (0.2L/ha): Cornflower <i>Centaurea cyanus</i> CENCY <u>Tolerant weed (0.2 L/ha):</u> Wild chamomile MATCH <i>Matricaria</i> <i>chamomilla</i>									

Remarks (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
table (b) Catalogue of pesticide formulation types and international coding system CropLife
heading: International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be
given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out
when the notifier no longer supports this use.

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