FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: H-01-2022

Product name(s): Terbutylazyna 500 SC

Chemical active substance:

terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: ProAgri International Sp. z o.o.

Submission date: April 2024

MS Finalisation date: 11.2024; 03.2025

Version history

When	What
April 2024	Submission date
November 2024	ZRMs evaluated dRR submitted by Applicant.
March 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.

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	Not relevant.

0.1.3 Regulatory history of the active(s)

0.1.3.1 Terbuthylazine

Table 0.1-2: Summary of regulatory history of CAS No: 5915-41-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011 approving the active substance terbuthylazine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0820 Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione,

Status	
	spiroxamine, tefluthrin and terbuthylazine https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1550659094284&uri=CELEX:32019R0291 Commission Implementing Regulation (EU) 2021/824 of 21 May 2021 amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine https://eur-lex.europa.eu/eli/reg_impl/2021/824/oj
RMS	UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2012
Date of first Commission (re-registration) deadline (Step 1)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31/12/2024
Low risk substance or Candidate for Substitution?	N/A

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

Only uses as herbicide may be authorised.
Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.
In this overall assessment Member States must pay particular attention to:

- the consumer risk assessment from exposure to metabolites of terbuthylazine,
- the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions,
- the risk to mammals and earthworms

The SANCO report for terbuthylazine (SANCO/11337/2011 rev 3, 17 June 2011, 24 March 2021) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 23 May 2017 (EFSA Journal 2017;15(6):4868).

Table 0.1-3: Information on minimum purity of terbuthylazine

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**Minimum purity of active substance used in the product / information on available equivalency report *, **
minimum purity of active substance: 950 g/kg	~~CONFIDENTIAL information provided separately (Part C).~~ Min purity of active substance: 980 g/Kg Equivalence report available: Y RMS: PL (December 2021)

* 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: 1-2
Residues section: 1-2
Environmental fate section: 1-2
Ecotoxicology section: 1,2 for the maximum dose 500 g s.a./ha.

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

Efficacy section: none
Toxicology section: none
Residues section: none
Fate section: none for the maximum dose 500 g s.a./ha. The risk for earthworm-eating mammals due to exposure via bioaccumulation in earthworms (secondary poisoning) for the maximum rate of 750 g as/ha should be provided.
Ecotoxicology section: none.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS: none

All uses/ GAPs are covered by established MRLs.

Efficacy section: Terbutylazyna 500 SC can be granted in Poland for pre-emergence (BBCH 00) or early post-emergence use (BBCH 12-16) use against weeds on maize at recommended dose 1,0 L/ha and 1,5 L/ha. Accepted water volume is 150-300 L/ha. Product can be used only once a season.

Mammalian toxicology:

Classification of TERBUTYLOAZYNA 500 SC is: Acute Tox.4/H302; Eye Irrit.2/H319; Skin Sens.1/H317;STOT RE 2/H373.

According to the model calculations, it can be concluded that the risk to the operator using Terbuthylazine 500 SC according to the intended use presented in the GAP table is acceptable if the operator is equipped with work clothes (covered arms, body and legs) and protective gloves during mixing/loading and does not pose a health risk to the employee if work clothes are used (covered arms, body and legs). Accidental short-term exposure of bystanders and residents (children and adults) to terbuthylazine does not pose a health risk if risk mitigation measures are applied. During spraying, a protection zone of at least 5 m from

residential buildings/habitats and bystanders should be maintained.

Metabolism and residues section: uses are accepted

Risk mitigation measures recommended for rotational crops: one year plant-back interval or deep ploughing (more than 20 cm soil mixing) to dilute soil concentrations noting that a ploughing depth of 30 cm reduces soil residues by a factor of 1.5 and a ploughing depth of 40 cm by 50 %. (according to the EFSA Journal 2020;18(1):5980).

Fate section:

No risk for groundwater is expected, if will using according GAP and one application eve-ry three years on the same field.

Ecotoxicology section:

The risk for earthworm-eating mammals due to exposure via bioaccumulation in earthworms (secondary poisoning) for the maximum rate of 750 g as/ha should be provided. The refinement risk assessment for mammals should be considered by MSs level.

The refinement risk assessment for birds for maximum dose rate at 750 g s.a./ha performed by Applicant for wood pigeon based on the PD refinement value based on Ljunggren (1968) study may be questioned. The Applicant should complete the informations:

1. Justification to use the study from Sweden (northern zone).
2. Please also discuss if the PD study was performed in a maize environment, in the correct season. Was the diet based on volume percentages, or mass percentage or something else? Were correct conversion factors be considered? etc. Please check appendix Q in the guidance.

The refinement risk assessment for birds should be considered by MSs level.
The Applicant should provide a comparison of these formulations in terms of their toxicity to different groups of organisms and also a comparison of their physicochemical properties (amount of active substance in the formulation, type of formulation, composition) in dRR B9 and in document C. In order to demonstrate that both formulations are comparable in terms of ecotoxicology or that the formulation used in the higher-tier risk assessment is a worse case. The risk assessment for earthworms should be considered at the level of the Member States.

The following risk mitigation is required: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land or 50% nozzle reduction.

Appendix 1 ALL intended uses

GAP rev.1, date: 2022-11-28

PPP (product name/code):	H-01-2022	Formulation type:	SC [a, b]
Active substance 1:	terbuthylazine	Conc. of as 1:	500 g/L [c]
Safener:	n.a.	Conc. of safener:	n.a. [c]
Synergist:	n.a.	Conc. of synergist:	n.a. [c]
Applicant:	ProAgri International Sp. z o.o.	Professional use:	☒
Zone(s):	Central Zone [d]	Non professional use:	☐
Verified by MS:	no		

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 destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g 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	Maize	F	Weeds. For details, please refer to dRR Part B3	broadcast spraying	BBCH 00	a) 1 b) 1	NA	a) 1.0-~~1.5~~ L/ha b) 1.0-~~1.5~~ L/ha	500-~~750~~ g as/ha	~~100-400~~ 150-300 L/ha	N/A	Targeted range: 1.0-~~1.5~~ L/ha every 3 years **Eff. section**: recommended water volume is 150-300 L/ha **Ecotox section**: For a dose of 750 g/ha the refinement risk assessment for earth-

													worm-eating mammals was not accepted.
2	Poland	Mazie	F		broadcast spraying	BBCH 12-16	a) 1 b) 1	NA	a) 1.0-~~1.5~~ L/ha b) 1.0-~~1.5~~ L/ha	500-~~750~~ g as/ha	~~100-400~~ 150-300 L/ha	N/A	Targeted range: 1.0-~~1.5~~ L/ha every 3 years **Eff. section**: recommended water volume is 150-300 L/ha. **Ecotox section**: For a dose of 750 g/ha the refinement risk assessment for earthworm-eating mammals was not accepted.

Remarks table heading:

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

Remarks columns:

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