FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: **TERBUT 500 SC**

Product names: **TERBUT 500 SC/**

TAZOPRYM 500SC / CORNAO 500 SC

Chemical active substance:

Terbuthylazine, 500 g/L

Central

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

Finalisation date: 10/2021; 03/2022; 06/2022

Version history

When	What
10/2021	ZRMS evaluated the updated dRR by Applicant.
March 2022	Final Registration Report
June 2022	Review of the assessment taking into account 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

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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. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

This dossier has been submitted in order to register new product.
On 1 January 2017 data protection period for existing active substance **Terbuthylazine** has been terminated.
Taking into account above applicant shall be exempted from supplying the test and study in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Not relevant as the product has not yet been authorised in any zone.

Table 0.1-1: Overview of zRMS and cMS

Not relevant as the product has not yet been authorised.

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: ~~133-06-02~~ 5915-41-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	~~ES~~ 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) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31.12.2024
Low risk substance or Candidate for Substitution?	No

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 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.2 – 17/06/2011) 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 10 January 2011.

Table 0.1-3: Information on minimum purity of ~~Fludioxonil~~ Therbuthylazine

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
950 g/kg	For minimum purity of active substance see part C For details regarding specification of the active substacne see also in part C

* 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.

Comments of zRMS:	The active ingredient source used are approved at EU level. The information on the equivalence of the active substance sources has been provided by the Applicant to the Polish Ministry of Agriculture and Rural Development (LoA) and attached to this application.

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 (solo and mixture tank with adjuvant) and 2 (only mixture tank with adjuvant)

Residues section: 1-2

Environmental fate and behavior section: 1-2

Ecotoxicology section: 2

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

Efficacy section: 2 (solo use)

Residues section: none

Environmental fate and behavior section: none

Ecotoxicology section: 1

Metabolism and Residues
All uses/ GAPs are covered by established MRLs.

Conclusions:

Efficacy section:
Only solo use can be accepted at post-emergence use. Use in the mixture tank with adjuvant is accepted for pre- and post-emergence use. Detailed assessment is presented in RR B3.

Metabolism and Residues

MRL for terbutylazine in maize was proposed to change from 0.1 mg/kg to 0.01* mg/kg (SANTE/10444/2020)

The new Regulation has not been published yet and therefore it is not in place. New information to justify the application should be provided after the entry into force of the new Regulation.

Mammalian toxicology:

TERBUT 500 SC is classified: H302/Acute Tox.4; H317 /Skin Sens.1; H373/ STOT RE 2. Not risk for operator, worker and bystander / resident (child & adult) and is acceptable under the conditions of the intended use.

Commission Implementing Regulation (EU) 2021/824 of 21 May 2021: Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.

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Appendix 1 ALL intended uses

PPP (product name/code):	Terbut 500 SC, Tezoprym 500 SC, Cornao 500 SC/ Terbut 500 SC		GAP rev. 1, date: 04.2020
Active substance 1:	terbuthylazine	Formulation type:	suspension concentrate (SC)
Applicant:	Synthos Agro sp. Z o.o.	Conc. of as 1:	500 g/L
Zone(s):	central	Professional use:	☒
Verified by MS:	no	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 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)	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~~	~~PL~~	~~Maize (post-emergence)~~	~~F~~	~~**Sensitive:**~~ ~~*Capsella bursa-pastoris*~~ ~~*Viola arvensis*~~ ~~*Chenopodium album*~~ ~~*Amaranthus retroflexus*~~ ~~*Galium aparine*~~ ~~*Tripleurospermum inodorum*~~ ~~*Veronica arvensis*~~ ~~*Fallopia convolvulus*~~ ~~*Solanum nigrum*~~ ~~*Matricaria Chamomilla*~~ ~~**Medium sensitive:**~~ ~~*Cyanus segetum*~~ ~~*Stellaria media*~~	~~Fine spraying~~	~~BBCH 12-16~~	~~1~~	~~-~~	~~1 l/ha~~	~~500 g as/ha~~	~~200-300 l/ha~~		Ecotoxicology section not accepted this use.
				~~**Sensitive:**~~ ~~*Chenopodium album*~~ ~~*Viola arvensis*~~ ~~*Amaranthus retroflexus*~~ ~~*Galium aparine*~~ ~~*Tripleurospermum inodorum*~~	~~Fine spraying~~	~~BBCH 12-16~~	~~1~~	~~-~~	~~1 l/ha + 0,2 (adiuwant)~~	~~500 g as/ha~~	~~200-300 l/ha~~		Ecotoxicology section not accepted this use.

				~~*Capsella bursa-pastoris*~~ ~~*Veronica arvensis*~~ ~~*Fallopia convolvulus*~~ ~~*Solanum nigrum*~~ ~~*Matricaria Chamomilla*~~ ~~*Stellaria media*~~ ~~**Medium sensitive**~~: ~~*Cyanus segetum*~~									
2	PL	Maize (pre-emergence)	F	~~**Sensitive:**~~ ~~*Chenopodium album*~~ ~~*Viola arvensis*~~ ~~*Amaranthus retroflexus*~~ ~~*Tripleurospermum inodorum*~~ ~~*Matricaria Chamomilla*~~ ~~**Medium sensitive:**~~ ~~*Stellaria media*~~ ~~*Cyanus segetum*~~	~~Fine spraying~~	~~BBCH 00~~	~~1~~	~~-~~	~~1 l/ha~~	~~500 g as/ha~~	~~200-300 l/ha~~		Efficacy section not accepted this use. Commission Implementing Regulation (EU) 2021/824 of 21 May 2021: Use shall be limited to one applica-tion every three years on the same field at a maximum dose of 850 g ter-buthylazine per hectare.
				Sensitive: *Viola arvensis* *Amaranthus retroflexus* *Tripleurospermum inodorum* *Capsella bursa-pastoris* ~~*Matricaria Chamomilla*~~ **Medium sensitive:** *Fallopia convolvulus* *Geranium pusillum* *Galium aparine* *Cyanus segetum* *Stellaria media* *Chenopodium album*	Fine spraying	BBCH 00	1	-	1 l/ha + 0,2 l/ha (adiuwant)	500 g as/ha	200-300 l/ha		Commission Implementing Regulation (EU) 2021/824 of 21 May 2021: Use shall be limited to one applica-tion every three years on the same field at a maximum dose of 850 g ter-buthylazine per hectare.

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