

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: TERBUT 500 SC

Product name(s): La Zina 500 SC; Tekno 500 SC

Chemical active substance(s):

Terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: PUH Chemirol Sp. z o.o.

Submission date: November 2019

MS Finalisation date: **January 2022**; June 2022

Version history

When	What
January 2022	RMS finalised dRR assessment
June 2022	Final Version after Commenting period

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0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for zonal registration of TERBUT 500 SC containing Terbutylazine in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to TERBUT 500 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of TERBUT 500 SC have been made using endpoints agreed in the EU review of Terbutylazine.

This document describes the specific conditions of use and labelling required for the registration (La Zina 500 SC; Tekno 500 SC) of product code TERBUT 500 SC.

0.1.1 Reason for application

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

In addition to the submission of studies as listed in section(s) B1-B10, 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 TERBU 500 SC La Zina 500 SC; Tekno 500 SC	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Terbutylazine

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

Status	
Approved in EU	Y

Status	
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011
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) or date of deadline for renewal of authorization (renewal)	31/12/2021
Date of final Commission (re-registration) deadline (Step 2)	31/12/2021
Current expiration of approval	31/12/2021 31/12/2024
Low risk substance or Candidate for Substitution?	LRS

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 long-term risk and the risk from secondary poisoning for mammals and the risk for earthworms.

Conditions of use shall include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

The SANCO report for Terbutylazine SANCO/11337/2011 rev 2- 17 June 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 10/01/2011.

Table 0.1-3: Information on minimum purity of Terbutylazine

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalence report
950 g/kg	For the purity of active substance, please refer to PART C- confidential information Equivalence report available: Y (available on CIRCA) RMS:UK (CRD)

0.1.4 Regulatory history of the product (if relevant)

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: 2, 3 and 4
 Mammalian toxicology section: 1-4
 Residues section: 1-4
 Environmental fate and behavior section: 1-4
 Ecotoxicology section: 1 with restriction to use from BBCH 00-05

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

Efficacy section: 1
Mammalian toxicology section: none
Residues section: none
Environmental fate and behavior section: none
Ecotoxicology section: uses from BBCH 10-12

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:

Ecotox Section:

The risk mitigation measures for aquatic organism and for non-target plants should be considered at MSs level. Further refinement is required for post-emergence application for mammals (BBCH 10-12).

Metabolism and Residues:

Accepted use/ GAP is covered by established MRLs

Conclusions:

Physical and chemical properties section:

No data gaps.

Efficacy section:

Only use solo pre-emergence on maize can not be accepted. Detailed assessment is presented in dRR B3. Use pre-emergence with adjuvant and solo and with adjuvant post-emergence is accepted. Listed of accepted weed species are included in label and dRR B3 and A.

Section 6, Mammalian toxicology

Based on the toxicological data in accordance with the provisions of the Regulation EC 1272/2008, the formulation TERBUT 500 SC (La Zina 500 SC; Tekno 500 SC) requires classification in respect to target organ toxicity in case of repetitive exposure as STOT RE 2, H373

Exposure data:

Operator: According to the estimations based on AOEM, the use of Terbut 500 SC (La Zina 500 SC; Tekno 500 SC) causes acceptable health risk for operator equipped with PPE (protective gloves) and work wear during mixing and loading.

Worker: According to the estimation results, the use of Terbut 500 SC (La Zina 500 SC; Tekno 500 SC) contain-ing terbuthylazine (500 g/L) does not cause unacceptable health risk for a worker wearing work wear and protective gloves during field inspection, even in case of 8h exposure.

Bystander/Resident: The exposure of bystander and resident (children and adult) to Terbut 500 SC (La Zina 500 SC; Tekno 500 SC) causes acceptable risk to human health if:

- min. 5-meter buffer zone is kept during spraying,
- drift-reduction nozzles are used.

Metabolism and Residues

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).

Uses with adjuvant are accepted

According to the SANCO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.

Appendix 1 ALL intended uses

Appendix 2

GAP rev., date: 01.2022

PPP (product name/code): La Zina 500 SC/Tekno 500 SC
Terbut 500 SC

Active substance 1: terbuthylazine

Active substance 2: -

Active substance 3: -

Safener: -

Synergist: -

Applicant: Innvigo Sp. z o.o.

Zone(s): Central^(d)

Verified by MS: yes

Field of use: Herbicide

Formulation type: SC^(a, b)

Conc. of as 1: 500 g/l^(c)

Conc. of as 2: ^(c)

Conc. of as 3: ^(c)

Conc. of safener: ^(c)

Conc. of synergist: ^(c)

Professional use:

Non professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop desti- nation / purpose of crop)	F, Fn, G, Gn, Gnp or I**	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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 Zea mays (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 00- 05	a)1 b)1	n/a	a) 1.0 l/ha b) 1.0 l/ha	a) 0.5 kg a.s./ha b) 0.5 kg a.s./ha	200-300	n/a	According to the SAN- CO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a max- imum rate of 850 g/ha	Efficacy: Not accepted.
2	PL	Maize Zea mays (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 00- 05	a)1 b)1	n/a	a) 1.0 l/ha + 0,2 % v/v Hydra- vance 100 LQ b) 1.0 l/ha + 0,2 % v/v Hydra- vance 100 LQ	a) 0.5 kg a.s./ha + 0,2 % v/v Hydravance 100 LQ b) 0.5 kg a.s./ha + 0,2 % v/v Hydravance 100 LQ	200-300	n/a	According to the SAN- CO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a max- imum rate of 850 g/ha	
3	PL	Maize Zea mays (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 12- 16	a)1 b)1	n/a	a) 1.0 l/ha b) 1.0 l/ha	a) 0.5 kg a.s./ha b) 0.5 kg a.s./ha	200-300	n/a	According to the SAN- CO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a max- imum rate of 850 g/ha	Ecotox: Not accepted
4	PL	Maize Zea mays (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 12- 16	a)1 b)1	n/a	a) 1.0 l/ha + 0,2 % v/v Hydra- vance 100 LQ b) 1.0 l/ha + 0,2 % v/v Hydra- vance 100 LQ	a) 0.5 kg a.s./ha + 0,2 % v/v Hydravance 100 LQ b) 0.5 kg a.s./ha + 0,2 % v/v Hydravance	200-300	n/a	According to the SAN- CO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a max- imum rate of 850 g/ha	Ecotox: Not accepted

											100 LQ								
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																			
5																			
6																			
Minor uses according to Article 51 (field uses)																			
7																			
8																			
Minor uses according to Article 51 (interzonal uses)																			
9																			
10																			

Hydravance 100 LQ - Adjuvant

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/m ³ 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