

# 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**

|                     | <b>zRMS, product name and authorization no. (if relevant)</b> | <b>(if relevant) Concerned MS, MS' product name and authorization number (if applicable)</b> |
|---------------------|---|--|
| <b>Central zone</b> | POLAND<br>TERBU 500 SC<br>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**

|                |   |
|----------------|---|
| <b>Status</b>  |   |
| Approved in EU | Y |

|  |  |
|--|--|
| <b>Status</b>  |  |
| Original Inclusion Directive<br>or<br>Commission Implementing Regulation   | Commission Implementing Regulation (EU)<br>No 820/2011 of 16 August 2011 |
| RMS  | UK   |
| Date of Approval (or most recent renewal) of Active Substance<br>(date of Regulation to be applied)                        | 01/01/2012   |
| Date of first Commission (re-registration) deadline (Step 1) or date of<br>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   | <del>31/12/2021</del> 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<br>or Implementing regulation | (if different) Minimum purity of active substance<br>used in the product / information on available equivalence<br>report  |
|---|--|
| 950 g/kg  | For the purity of active substance, please refer to PART<br>C- confidential information<br>Equivalence report available: Y ( available on CIRCA)<br>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<sup>(d)</sup>

Verified by MS: yes

Field of use: Herbicide

Formulation type: SC<sup>(a, b)</sup>

Conc. of as 1: 500 g/l<sup>(c)</sup>

Conc. of as 2: <sup>(c)</sup>

Conc. of as 3: <sup>(c)</sup>

Conc. of safener: <sup>(c)</sup>

Conc. of synergist: <sup>(c)</sup>

Professional use: ☒

Non professional use: ☐

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



[illegible]

## Hydravance 100 LQ - Adjuvant

|                               |     |  |     |   |
|-------------------------------|-----|--|-----|---|
| <b>Remarks table heading:</b> | (a) | e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)   | (d) | Select relevant   |
|                               | (b) | Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  | (e) | Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1   |
|                               | (c) | g/kg or g/l  | (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.  |
| <b>Remarks columns:</b>       | 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<br>Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.  | 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   |
|                               |     |  |     |   |
|                               |     |  |     |   |