

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: H-01-2022

Product name: Terbutylazyna 500 SC

Chemical active substances:

terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: ProAgri International Sp. z o.o.

Submission date: April 2024

MS Finalisation date: 01.2025; 03.2025

Version history

| When | What |
|--------------|---|
| April 2024 | Submission date |
| January 2025 | ZRMs evaluated dRR submitted by Applicant |
| March 2025 | The final Registration Report |
| | |

Table of Contents

| | | |
|----------|---|-----------|
| 1 | Details of the application | 5 |
| 1.1 | Application background | 5 |
| 1.2 | Letters of Access | 5 |
| 1.3 | Justification for submission of tests and studies | 5 |
| 1.4 | Data protection claims | 5 |
| 2 | Details of the authorization decision | 5 |
| 2.1 | Product identity | 6 |
| 2.2 | Conclusion | 6 |
| 2.3 | Substances of concern for national monitoring | 7 |
| 2.4 | Classification and labelling | 7 |
| 2.4.1 | Classification and labelling under Regulation (EC) No 1272/2008 | 7 |
| 2.4.2 | Standard phrases under Regulation (EU) No 547/2011 | 8 |
| 2.4.3 | Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) | 9 |
| 2.5 | Risk management | 9 |
| 2.5.1 | Restrictions linked to the PPP | 9 |
| 2.5.2 | Specific restrictions linked to the intended uses | 9 |
| 2.6 | Intended uses (only NATIONAL GAP) | 11 |
| 3 | Background of authorization decision and risk management | 14 |
| 3.1 | Physical and chemical properties (Part B, Section 2) | 14 |
| 3.2 | Efficacy (Part B, Section 3) | 14 |
| 3.3 | Efficacy data | 14 |
| 3.3.1 | Information on the occurrence or possible occurrence of the development of resistance | 18 |
| 3.3.2 | Adverse effects on treated crops | 20 |
| 3.3.3 | Observations on other undesirable or unintended side-effects | 21 |
| 3.4 | Methods of analysis (Part B, Section 5) | 23 |
| 3.4.1 | Analytical method for the formulation | 23 |
| 3.4.2 | Analytical methods for residues | 23 |
| 3.5 | Mammalian toxicology (Part B, Section 6) | 23 |
| 3.5.1 | Acute toxicity | 24 |
| 3.5.2 | Operator exposure | 24 |
| 3.5.3 | Worker exposure | 24 |
| 3.5.4 | Bystander and resident exposure | 25 |
| 3.6 | Residues and consumer exposure (Part B, Section 7) | 25 |
| 3.6.1 | Residues | 25 |
| 3.6.2 | Consumer exposure | 27 |
| 3.7 | Environmental fate and behaviour (Part B, Section 8) | 28 |
| 3.7.1 | Predicted environmental concentrations in soil (PEC _{soil}) | 28 |
| 3.7.2 | Predicted environmental concentrations in groundwater (PEC _{gw}) | 28 |
| 3.7.3 | Predicted environmental concentrations in surface water (PEC _{sw}) | 28 |
| 3.7.4 | Predicted environmental concentrations in air (PEC _{air}) | 28 |
| 3.8 | Ecotoxicology (Part B, Section 9) | 29 |

| | | |
|-------------------|--|-----------|
| 3.8.1 | Effects on terrestrial vertebrates | 29 |
| 3.8.2 | Effects on aquatic species | 29 |
| 3.8.3 | Effects on bees | 30 |
| 3.8.4 | Effects on other arthropod species other than bees..... | 30 |
| 3.8.5 | Effects on soil organisms | 30 |
| 3.8.6 | Effects on non-target terrestrial plants | 31 |
| 3.8.7 | Effects on other terrestrial organisms (Flora and Fauna)..... | 31 |
| 3.9 | Relevance of metabolites (Part B, Section 10) | 32 |
| 4 | Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) | 32 |
| 5 | Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization | 32 |
| Appendix 1 | Copy of the product authorization | 33 |
| Appendix 2 | Copy of the product label | 34 |
| Appendix 3 | Letter of Access | 41 |
| Appendix 4 | Lists of data considered for national authorization..... | 42 |

PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for the registration in Poland of plant protection product named H-01-2022, containing terbuthylazine, 500 g/L.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C.

The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to H-01-2022 where that data has not been considered in the EU review. Otherwise, assessments for the safe use of H-01-2022 have been made using endpoints agreed in the EU review of terbuthylazine.

This document describes the specific conditions of use and labelling required for Poland for the registration of plant protection product H-01-2022.

1.1 Application background

This application is submitted by ProAgri International Sp. z o.o.

This is the application for registration plant protection product under name of H-01-2022 according to Article 33 of Regulation 1107/2009. Product H-01-2022 is a suspension concentrate (SC), containing 500 g/L of terbuthylazine to be used as a herbicide to protect maize.

1.2 Letters of Access

Letters of Access are submitted as separate annexes to this application.

1.3 Justification for submission of tests and studies

In order to address the product data requirements, the applicant is submitting a complete product data package in line with the requirements of Regulation (EU) No. 284/2013.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of product H-01-2022, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 – 10, Part C and in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

| | |
|--|--|
| Product code | H-01-2022 |
| Product name in MS | Terbutylazyna 500 SC |
| Authorization number | N/A |
| Function | herbicide |
| Applicant | ProAgri International Sp. z o.o. |
| Active substance(s) (incl. content) | terbuthylazine, 500 g/L |
| Formulation type | suspension concentrate [SC] |
| Packaging | 1 L 5 L, 10 L, 20 L - f-HDPE (fluorinated HDPE) Professional user |
| Coformulants of concern for national authorizations | N/A |
| Restrictions related to identity | N/A |
| Mandatory tank mixtures | N/A |
| Recommended tank mixtures | N/A |

2.2 Conclusion

The evaluation of the application for the formulation **H-01-2022 (Terbutylazyna 500 SC)** resulted in a decision to grant the authorisation.

Physical and chemical properties:

Data gap - shelf life study. The study should be submitted when finished (estimated study completion date - February/March 2025).

Efficacy section: Terbutylazyna 500 SC can be granted in Poland for pre-emergence (BBCH 00) or early post-emergence (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 pre- or early post-emergence.

Mammalian toxicology:

Classification of Terbutylazyna 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 Terbutylazyna 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: 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:

The evaluation of the application for product Terbutylazyna 500 SC resulted in the decision to grant the authorization and following risk mitigation is required: to protect groundwater respect one application every three years on the same field.

Ecotoxicology section:

Uses are accepted 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. 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.

Evaluators verified whether the co-formulants contained in plant protection product **H-01-2022** are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023. Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product **H-01-2022** does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product **H-01-2022** meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in the dRR Part C and in the Annex to Part C (confidential).

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling




2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

| | |
|-------------------------------|---|
| Hazard class(es), categories: | Acute Tox. 4, H302 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT RE 2, H373 |
|-------------------------------|---|

| | |
|--|--|
| | Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |
|--|--|

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

| | |
|-------------------------------|---|
| Hazard pictograms: |    GHS07 GHS08 GHS09 |
| Signal word: | Warning |
| Hazard statement(s): | H302 - Harmful if swallowed. H319 - Causes serious eye irritation. H317 - May cause an allergic skin reaction. H373 - May cause damage to organs through prolonged or repeated exposure. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects. |
| Precautionary statement(s): | P260 - Do not breathe dust/fume/ gas/mist/vapours/spray P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301 + P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice/ attention. P302 + P352 - IF ON SKIN: Wash with plenty of water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 - Take off contaminated clothing and wash it before reuse. P314 - Get medical advice or attention if you feel unwell. P391 - Collect spillage. |
| Additional labelling phrases: | EUH401 - To avoid risks to man and the environment, comply with the instructions for use. |

| | |
|--|--|
| Special rule for labelling of plant protection product (PPP): | |
| EUH401 | To avoid risks to man and the environment, comply with the instructions for use. |
| Further labelling statements under Regulation (EC) No 1272/2008: | |
| - | - |

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

| | |
|------|---|
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| --- | To protect groundwater respect one application every three years on the same field. |
| SPe3 | To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5m to surface water bodies. |
| SPe3 | To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land |

| | |
|--|-------------------------|
| | or 50% nozzle reduction |
|--|-------------------------|

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

| | |
|---|---|
| - | - |
|---|---|

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

| | |
|---|---|
| Operator protection: | |
| - | Workwear (arms, body and legs covered) and gloves during mixing/loading and during application. |
| Worker protection: | |
| - | Workwear (arms, body and legs covered). Recommended: gloves when inspecting the treated crops. |
| Integrated pest management (IPM)/sustainable use: | |
| - | - |
| Environmental protection | |
| --- | To protect groundwater respect one application every three years on the same field. |
| SPe3 | To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5m to surface water bodies. |
| SPe3 | To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land or 50% nozzle reduction in case of 1.5 L/ha. |
| Other specific restrictions | |
| - | - |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

| | |
|---|---|
| Integrated pest management (IPM)/sustainable use: | |
| - | - |

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

| | | |
|---|---|----------------------|
| Integrated pest management (IPM)/sustainable use: | | Relevant for use no. |
| - | - | - |

| Environmental protection: | | Relevant for use no. |
|---------------------------|---|----------------------|
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). | 1, 2 |
| --- | To protect groundwater respect one application every three years on the same field. | 1,2 |
| SPe3 | To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5m to surface water bodies. | 1, 2 |
| SPe3 | To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land or 50% nozzle reduction | 1, 2 |

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1.0, date: 2022-11-28

PPP (product name/code): H-01-2022
 Active substance 1: terbuthylazine
 Safener: NA
 Synergist: NA
 Applicant: ProAgri International Sp. z o.o.
 Zone(s): central ^(d)
 Verified by MS: yes

Formulation type: SC ^(a, b)
 Conc. of as 1: 500 g/L ^(c)
 Conc. of safener: NA ^(c)
 Conc. of synergist: NA ^(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) | Member state(s) | Crop and/ or situation (crop destina- tion / purpose of crop) | F, Fn, G, Gn, Gpn 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 saf- ener/synergist per ha ^(f) |
| | | | | | Method / Kind | Timing / Growth stage of crop & sea- son | Max. number a) per use b) per crop/ season | Min. interval between ap- plications (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 | | |

H-01-2022

Part A - National Assessment

Applicant version

Version April 2024

| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | |
|--|----|-------|---|---|--------------------|------------|--------------|----|--|--|---------------------------------|-----|---|
| 1 | PL | 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 | a) 500- 750 g as/ha b) 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: accepted water volume is 150-300 L/ha. Fate section: 1.0-1.5 L/ha every 3 years Ecotox section: For a dose of 750 g/ha the refinement risk assessment for earthworm-eating mammals was not accepted. |
| 2 | PL | Maize | 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 | a) 500- 750 g as/ha b) 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: accepted water volume is 150-300 L/ha. Fate section: 1.0-1.5 L/ha every 3 years 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) | (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. |
| 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/m ³ 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 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 |

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that homogenous whitish liquid of characteristic odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 445°C. In aqueous 1% solution, it has a pH value around 6.05 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.33 % to 0.67 % v/v.

The product is not intended to be used in tank mixtures.

3.2 Efficacy (Part B, Section 3)

The purpose of this document is to provide data in support of an application for the registration of H-01-2022 (that was tested under the name of Terbutylazyna 500 SC) as a herbicide product to be used on maize in Poland (zRMS in charge of the evaluation of the dossier).

H-01-2022 is a suspension concentrate (SC) containing 500 g/L terbuthylazine. Active substance terbuthylazine was approved in accordance with Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011 approving the active substance terbuthylazine.

For the registration purpose, in 2022 8 efficacy trials were conducted against a broad spectrum of annual weeds in several maize varieties. In each performed trial the test product was applied pre-emergence and post-emergence at rates of 0.8 l/ha (400 g a.s./ha), 1.0 l/ha (500 g a.s./ha) and 1.5 l/ha (750 g a.s./ha).

All submitted trials were conducted in the North-East EPPO zone (Poland) under field conditions.

3.3 Efficacy data

Preliminary tests:

Terbuthylazine has been used as a herbicide since the 1960s. It is primarily used in maize and other crops to control broadleaf weeds and some grasses. Its effectiveness and relatively low cost have made it a popular choice for farmers over the decades. Like other triazine herbicides, it works by inhibiting photosynthesis in susceptible plants, making it a valuable tool in integrated weed management approaches. Generally, chemicals like Terbuthylazine became more broadly available in European agriculture in the 1970s and 1980s. In Poland, 21 PPPs with Terbuthylazine are registered in Poland and commonly used (on the basis on Ministry Register dated 16.10.2024). So, Terbuthylazine is registered and have been commonly used in agricultural practice for many years. Large scale efficacy trials are available to evaluate the effectiveness of products containing this active compound. Preliminary tests were not necessary in this case in the opinion of ZRMs.

MINIMUM EFFECTIVE DOSE:

The minimum effective dose of Terbuthylazine for controlling weeds in maize typically ranges from 1 to 2 kilograms per hectare. However, the exact dosage can vary based on several factors. Different weed have varying levels of susceptibility to Terbuthylazine. The soil's organic matter and texture can affect the herbicide's effectiveness. It is always crucial to follow label instructions.

The Applicant has proposed doses of Terbutylazyna 500 SC that reflect those of currently authorized Terbutylazine products across the EU. To provide information to establish the minimum effective dose (MED), some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in line to EPPO 1/225(2).

Applicant did not present separately MED trials. MED dose was studied in efficacy trials (8) carried out in one EPPO zone (N-E) in Poland in one growing season (2022). Applicant studied different doses: 0.8 L/ha; 1.0 L/ha and 1.5 L/ha during 8 efficacy trials. Applicant studied pre-emergence use (BBCH 00) and early post-emergence use (BBCH 12-16) at the same 8 trials. All trials were carried out on different varieties of maize.

Following varieties of maize were studied: DKC3595 (for grain and silage), Salamandra (for silage), Ulan (for grain and silage), Subito (for silage), Leonido (for grain and silage), DKC3088 (for grain), Amavit (for grain and bioethanol) and Danubio (for grain).

Below, ZRMs presented results for MED dose against Terbutylazyna 500 SC used pre-emergence (BBCH 00):

| EPPO code | Number of trials | 28-40 DA-A | | | 42-55 DA-A | | |
|-----------|------------------|------------|----------|----------|------------|----------|----------|
| | | 0,8 L/ha | 1,0 L/ha | 1,5 L/ha | 0,8 L/ha | 1,0 L/ha | 1,5 L/ha |
| CAPBP | 4 | 92,7 | 98,1 | 99,0 | 94,0 | 98,0 | 99,5 |
| GALAP | 3 | 78,1 | 89,4 | 91,6 | 79,8 | 88,8 | 92,3 |
| MATIN | 3 | 72,3 | 83,2 | 85,4 | 74,1 | 83,4 | 86,0 |
| AMARE | 3 | 83,2 | 92,6 | 96,3 | 81,4 | 92,0 | 94,9 |
| CHEAL | 3 | 72,4 | 84,9 | 86,2 | 72,9 | 85,3 | 86,2 |
| SOLNI | 3 | 72,7 | 84,3 | 86,4 | 76,2 | 86,1 | 88,3 |
| STEME | 3 | 94,3 | 100,0 | 100,0 | 94,8 | 100,0 | 100,0 |
| VERHE | 3 | 93,1 | 99,8 | 100,0 | 92,5 | 100,0 | 100,0 |
| GASPA | 2 | 90,7 | 100,0 | 100,0 | 91,2 | 100,0 | 100,0 |
| VIOAR | 2 | 73,8 | 84,8 | 86,1 | 74,4 | 84,5 | 85,9 |
| POLCO | 2 | 83,7 | 97,8 | 100,0 | 84,0 | 97,7 | 99,7 |
| SINAR | 2 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 |
| CENCY | 2 | 80,0 | 94,1 | 96,5 | 81,8 | 95,5 | 96,8 |
| THLAR | 2 | 90,9 | 92,5 | 92,5 | 90,3 | 92,8 | 92,7 |
| CIRAR | 1 | 77,5 | 85,0 | 86,0 | 76,8 | 86,0 | 86,5 |
| MYOAR | 1 | 98,0 | 100,0 | 100,0 | 98,8 | 100,0 | 100,0 |
| GAETE | 1 | 71,3 | 72,5 | 75,0 | 73,8 | 81,0 | 83,5 |

On the basis on obtained results it has been noted that:

- ✓ *for dose 0,8 L/ha* at 28-40 DA-A and 42-55 DA-A the efficacy was comparable. For dose 0,8 L/ha lack of tolerant and moderately tolerant weeds. Ten weeds (GALAP, MATIN, AMARE, CHEAL, SOLNI, VIOAR, POLCO, CENCY, CIRAR and GAETE) were classified as a moderately sensitive at 28-40 DA-A and 42-55 DA-A and 7 weeds were classified as a sensitive (CAPBP, STEME, VERHE, GASPA, SINAR, THLAR, MYOAR).
- ✓ *for dose 1,0 L/ha* at 28-40 DA-A and 42-55 DA-A the efficacy was comparable, in the exception of two weeds (CHEAL and SOLNI). At 28-40 DA-A and 42-55 DA-A lack of tolerant and moderately tolerant weeds. Five weeds were classified as a moderately sensitive (MATIN, CHEAL, SOLNI, VIOAR and GAETE) and twelve weeds were sensitive (CAPBP, GALAP, AMARE, STEME, VERHE, GASPA, POLCO, SINAR, CENCY, THLAR, CIRAR and MYOAR) at 28-40 DA-A. Three weeds were classified as a moderately sensitive (MATIN, VIOAR and GAETE) and fourteen weeds were sensitive (CAPBP, CHEAL, GALAP, AMARE, STEME, VERHE, GASPA, POLCO, SINAR, SOLNI, CENCY, THLAR, CIRAR and MYOAR) at 42-55 DA-A.
- ✓ *for dose 1,5 L/ha* at 28-40 DA-A and 42-55 DA-A the efficacy was comparable. Lack of tolerant and moderately tolerant weeds. One weed was classified as a moderately sensitive (GAETE) and sixteen weeds were sensitive (CAPBP, CHEAL, GALAP, AMARE, STEME, VERHE, GASPA, POLCO, SINAR, SOLNI, CENCY, THLAR, CIRAR, MYOAR, MATIN and VIOAR).

Below, ZRMs presented results for MED dose against Terbutylazyna 500 SC used post-emergence (BBCH 12-16):

| | | 14 DA-B | 28 DA-B |
|--|--|---------|---------|
|--|--|---------|---------|

| EPPO code | Number of trials | 0,8 L/ha | 1,0 L/ha | 1,5 L/ha | 0,8 L/ha | 1,0 L/ha | 1,5 L/ha |
|-----------|------------------|----------|----------|----------|----------|----------|----------|
| CAPBP | 4 | 76,7 | 81,9 | 84,5 | 85,1 | 95,7 | 96,8 |
| GALAP | 3 | 71,0 | 80,8 | 83,5 | 73,4 | 87,4 | 89,2 |
| MATIN | 3 | 62,5 | 70,4 | 73,3 | 69,2 | 78,9 | 82,4 |
| AMARE | 3 | 59,2 | 69,6 | 71,7 | 69,6 | 82,8 | 84,5 |
| CHEAL | 3 | 65,0 | 76,6 | 74,9 | 68,3 | 83,3 | 85,3 |
| SOLNI | 3 | 64,6 | 76,4 | 77,6 | 69,3 | 83,6 | 85,4 |
| STEME | 3 | 78,5 | 83,4 | 84,2 | 82,1 | 88,9 | 91,6 |
| VERHE | 3 | 82,8 | 86,8 | 88,6 | 84,0 | 89,5 | 93,1 |
| GASPA | 2 | 76,3 | 81,2 | 82,4 | 85,9 | 97,4 | 99,7 |
| VIOAR | 2 | 70,0 | 80,8 | 84,3 | 73,2 | 80,8 | 84,8 |
| POLCO | 2 | 66,8 | 71,4 | 75,9 | 79,3 | 89,6 | 91,5 |
| SINAR | 2 | 86,9 | 90,8 | 91,7 | 86,8 | 96,0 | 98,9 |
| CENCY | 2 | 69,4 | 79,7 | 81,5 | 74,9 | 85,3 | 87,4 |
| THLAR | 2 | 80,7 | 82,8 | 84,9 | 82,2 | 87,4 | 89,5 |
| CIRAR | 1 | 70,0 | 77,5 | 83,0 | 75,0 | 83,0 | 85,0 |
| MYOAR | 1 | 80,0 | 82,5 | 87,3 | 88,8 | 100,0 | 100,0 |
| GAETE | 1 | 65,0 | 65,0 | 70,0 | 67,5 | 78,8 | 82,8 |

On the basis on obtained results it has been noted that:

- ✓ *for dose 0,8 L/ha* at 14 DA-B and 28 DA-B the efficacy slightly differ. One weed was tolerant (AMARE), six were moderately tolerant (MATIN, CHEAL, SOLNI, POLCO, CENCY, GAETE), nine weeds were moderately sensitive (CAPBP, GALAP, STEME, VERHE, GASPA, VIOAR, THLAR, CIRAR, MYOAR) and one weed was sensitive (SINAR) at 14 DA-B. Lack of tolerant weeds, five weeds were moderately tolerant (AMARE, MATIN, CHEAL, SOLNI and GAETE), eight weeds were moderately sensitive (GALAP, STEME, VERHE, VIOAR, POLCO, CENCY, THLAR, CIRAR) and three weeds were sensitive (CAPBP, GASPA and MYOAR) at 28 DA-B.
- ✓ *for dose 1,0 L/ha* at 14 DA-B and 28 DA-B the efficacy slightly differ. Lack of tolerant weeds, two weeds were moderately tolerant (AMARE and GAETE), thirteen weeds were moderately susceptible (CAPBP, GALAP, MATIN, CHEAL, SOLNI, STEME, GASPA, VIOAR, POLCO, CENCY, THLAR, CIRAR and MYOAR) and two weeds were sensitive (VERHE and SINAR) at 14 DA-B. Lack of tolerant and moderately tolerant weeds, seven weeds were moderately susceptible (MATIN, AMARE, CHEAL, SOLNI, VIOAR, CIRAR and GAETE) and ten weed were sensitive (CAPBP, GALAP, STEME, VERHE, GASPA, POLCO, SINAR, CENCY, THLAR, and MYOAR) at 28 DA-B.
- ✓ *for dose 1,5 L/ha* at 14 DA-B and 28 DA-B efficacy results differ. Lack of tolerant and moderately tolerant weeds, fourteen weeds were classified as a moderately sensitive (CAPBP, GALAP, MATIN, AMARE, CHEAL, SOLNI, STEME, GASPA, VIOAR, POLCO, CENCY, THLAR, CIRAR and GAETE) and three weeds were sensitive (VERHE, SINAR and MYOAR) at 14 DA-B. Lack of tolerant and moderately tolerant weeds, four weeds were moderately sensitive (AMARE, MATIN, VIOAR and GAETE) and thirteen weeds were sensitive (CAPBP, GALAP, CHEAL, SOLNI, STEME, VERHE, GASPA, POLCO, SINAR, CENCY, THLAR, CIRAR and MYOAR).

Based on the results achieved on studied weeds during 8 maize trials for pre-emergence use and post-emergence use, it can be concluded that to consistently control frequently occurred weeds in maize, Terbutylazyna 500 SC should be applied once pre-emergence (BBCH 00) or post-emergence (BBCH 12-16) at dose 1.0-1.5 L/ha. Higher dose should be applied in the case of high infestation, high majority of weeds or worse weather conditions (ex. drought).

EFFICACY:

Terbutylazine is generally considered effective in controlling a broad spectrum of broadleaf and grassy weeds in maize cultivation. Terbutylazine effectively manages a wide range of weed species, including many annual grasses and broadleaf weeds that commonly affect maize fields. It can be applied before weed emergence or shortly after, allowing for flexibility in managing weed growth stages. The herbicide provides residual control, meaning it continuous to suppress weeds for period after application, reducing competition, during the critical growth stages of maize.

All detail's about efficacy methodology used during efficacy trials are presented above by Applicant. Submitted reports from field trials (8 in total) carried out in one EPPO zone (N-E) in Poland in one rowing season (2022). Applicant studied different doses: 0.8 L/ha; 1.0 L/ha and 1.5 L/ha during 8 efficacy trials. Applicant studied pre-emergence use (BBCH 00) and post-emergence use (BBCH 12-16) at the same 8 efficacy trials. All trials were carried out on different varieties of maize. Those trials include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying, etc.

Following varieties of maize were studied: DKC3595 (for grain and silage), Salamandra (for silage), Ulan (for grain and silage), Subito (for silage), Leonido (for grain and silage), DKC3088 (for grain), Amavit (for grain and bioethanol) and Danubio (for grain). Applicant properly presented results separately for pre-emergence and post-emergence use. Only trials with greater than 4-5 weeds/m² or over 2% ground cover should be taken for assessment. According to EPPO PP 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds should be required. According to Polish rules for major weeds – at least 4 trials are required and for minor weeds – at least 2 trials.

Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Only one exception was noted (conducting studies during one growing season). Applicant presented explanations about this. In the opinion of ZRMs, trials from one growing season for known active substance such as Terbutylazine should be accepted.

Applicant classified the sensitivity of weeds by SANCO scale. However, weeds should be classified in line to sensitivity scale accepted by Polish harmonization agreements and in line with the farmer's habit. So, ZRMs used following weed scale: sensitivity weeds (S) >85% eff.; moderately sensitivity (MS) 70-85%; moderately tolerant (MT) 60-70% and tolerant weeds (T) <60%.

Applicant studied following weeds species during trials for pre-emergence and post-emergence use: CAPBP (4 trials), GALAP (3), MATIN (3), AMARE (3), CHEAL (3), SOLNI (3), STEME (3), VERHE (3), GASPA (2), VIOAR (2), POLCO (2), SINAR (2), CENCY (2), THLAR (2), CIRAR (1), MYOAR (1) and GAETE (1).

Weeds studied only in one trial (CIRAR, MYOAR and GAETE) should be not taken to assessment due to not acceptable number of trials. Those major weeds in maize: AMARE (3 trials), CHEAL (3 trials), SOLNI (3 trials) and POLCO (2 trials) were characterized by not sufficient number of trials (at least 4 are required), so they should be excluded from GAP table and label project.

Following weeds can be acceptable in GAP table and label project: CAPBP, GALAP, MATIN, STEME, VERHE, GASPA, VIOAR, SINAR, CENCY and THLAR.

Pre-emergence use:

| EPPO code | Number of trials | 28-40 DA-A | | | 42-55 DA-A | | |
|-----------|------------------|------------|----------|------------------|------------|----------|------------------|
| | | 1,0 L/ha | 1,5 L/ha | st. ref. product | 1,0 L/ha | 1,5 L/ha | st. ref. product |
| CAPBP | 4 | 98,1 | 99,0 | 97,2 | 98,0 | 99,5 | 98,0 |
| GALAP | 3 | 89,4 | 91,6 | 90,1 | 88,8 | 92,3 | 89,8 |
| MATIN | 3 | 83,2 | 85,4 | 83,3 | 83,4 | 86,0 | 83,3 |
| STEME | 3 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 |
| VERHE | 3 | 99,8 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 |
| GASPA | 2 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 |
| VIOAR | 2 | 84,8 | 86,1 | 84,5 | 84,5 | 85,9 | 85,9 |
| SINAR | 2 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 | 100,0 |
| CENCY | 2 | 94,1 | 96,5 | 96,8 | 95,5 | 96,8 | 95,9 |
| THLAR | 2 | 92,5 | 92,5 | 92,2 | 92,8 | 92,7 | 93,4 |

On the basis of noted results it can be concluded that MATIN and VIOAR are moderately weeds and CAPBP, GALAP, STEME, VERHE, GASPA, SINAR, CENCY and THLAR are sensitive weeds at dose 1,0 L/ha of Terbutylazyna 500 SC. All studied weeds were sensitive against dose 1,5 L/ha. Results were comparable to st. ref. product (Tezosar 500 SC used at dose 1,0 L/ha).

Post-emergence use:

| EPPO code | Number of trials | 14 DA-B | | | 28 DA-B | | |
|-----------|------------------|----------|----------|------------------|----------|----------|------------------|
| | | 1,0 L/ha | 1,5 L/ha | st. ref. product | 1,0 L/ha | 1,5 L/ha | st. ref. product |
| CAPBP | 4 | 81,9 | 84,5 | 82,0 | 95,7 | 96,8 | 95,4 |

| | | | | | | | |
|--------------|---|------|------|------|------|------|------|
| GALAP | 3 | 80,8 | 83,5 | 81,1 | 87,4 | 89,2 | 86,4 |
| MATIN | 3 | 70,4 | 73,3 | 70,0 | 78,9 | 82,4 | 80,1 |
| STEME | 3 | 83,4 | 84,2 | 83,3 | 88,9 | 91,6 | 89,0 |
| VERHE | 3 | 86,8 | 88,6 | 86,3 | 89,5 | 93,1 | 89,6 |
| GASPA | 2 | 81,2 | 82,4 | 81,8 | 97,4 | 99,7 | 96,5 |
| VIOAR | 2 | 80,8 | 84,3 | 80,7 | 80,8 | 84,8 | 83,3 |
| SINAR | 2 | 90,8 | 91,7 | 90,3 | 96,0 | 98,9 | 96,3 |
| CENCY | 2 | 79,7 | 81,5 | 78,8 | 85,3 | 87,4 | 86,2 |
| THLAR | 2 | 82,8 | 84,9 | 82,2 | 87,4 | 89,5 | 87,2 |

On the basis of noted results it can be concluded that CAPBP, GALAP, STEME, VERHE, GASPA, SINAR, CENCY and THLAR are sensitive weeds at dose 1,0 L/ha and 1,5 L/ha of Terbutylazyna 500 SC. MATIN and VIOAR are moderately sensitive against Terbutylazyna 500 SC used at dose 1,0 L/ha and 1,5 L/ha. Results were comparable to st. ref. product (Tezosar 500 SC used at dose 1,0 L/ha).

Summary: The most effective for most studied weed species for pre- and post-emergence use on maize was dose 1,0 L/ha and 1,5 L/ha. The rate should be adjusted according to the development stage of the weeds and the weed species present in the field. The lower rate should be applied to weeds that are less developed, in the higher of the recommended dose should be applied when weeds are more advanced in development (post-emergence use) and worse agro-weather conditions (for ex. drought for pre- and post-emergence use).

In Polish label following weeds species can be included:

✓ **Pre-emergence use:**

Dose 1,0 L/ha: susceptible weeds: CAPBP, GALAP, STEME, VERHE, GASPA, SINAR, CENCY and THLAR; moderately susceptible: MATIN and VIOAR

Dose 1,5 L/ha: susceptible weeds: CAPBP, GALAP, STEME, VERHE, GASPA, SINAR, CENCY, THLAR, MATIN and VIOAR.

✓ **Post-emergence use:**

Dose 1,0 L/ha: susceptible weeds: CAPBP, GALAP, STEME, VERHE, GASPA, SINAR, CENCY and THLAR, moderately susceptible: MATIN and VIOAR.

Dose 1,5 L/ha: susceptible weeds: CAPBP, GALAP, STEME, VERHE, GASPA, SINAR, CENCY and THLAR; moderately susceptible weeds: MATIN, VIOAR.

ZRMs not accepted proposed by Applicant water volume: 100-400 L/ha. During trials only 300 L/ha was studied. Reference product (Tezosar 500 SC) is registered for use at 150-300 L/ha. So, ZRMs recommended also volume 150-300 L/ha for Terbutylazyna 500 SC.

ZRMs accepted proposed by Applicant application window for pre-emergence use (BBCH 00) and post-emergence use (BBCH 12-16) as in line to submitted and assessed trials.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Maize (*Zea mays* L.) production continues to grow globally, including in Central Europe (Andr et al., 2014), and this trend is expected to persist (Tatsumi et al., 2011). Maize is also the main crop for biogas production (Amon et al., 2007). Effective weed control is crucial for maize growth, as it has limited competitive ability (Ghanizadeh et al., 2014). Due to its sowing period in Europe, a diverse weed flora of grasses and broadleaf species is common (Baghestani et al., 2007; Kolářová et al., 2014; Pannacci & Tei, 2014). Traditionally, pre-emergence terbuthylazine applications have been used to control these weeds due to its broad spectrum, long-lasting effect, maize tolerance, and efficacy (Schulte et al., 2012). However, short rotations or maize monoculture with repeated herbicide use have increased difficult to control weeds, prompting farmers to use more diverse strategies (Meissle et al., 2010). In 2004, terbuthylazine continuous to be a major component of herbicide programs in Europe, especially in maize. At a country level, the Netherlands treats almost 100% of maize, while on the low end, Austria treats 35% of maize hectares with terbuthylazine. Approxi-

mately 60% of the combined area in maize production in Europe received terbuthylazine, including Germany, Italy and Belgium. Terbuthylazine is used in more than 45 countries and remains a key weed control tool in crops such as maize, sorghum, pea, bean, lupine, grape, pome fruit, citrus and vine (Bruce et al. 208). Like many herbicides, there is a concern about weeds developing resistance to terbuthylazine over time due to repeated and extensive use.

Terbuthylazine is a triazine herbicide that inhibits photosynthesis in target plants by binding to the photosystem II complex. Resistance to Terbuthylazine and related triazine herbicides has been documented in some weed species. The development of resistance occurs primarily through genetic mutations in the weed population that alter the target site of the herbicide, reducing its effectiveness. Photosystem II inhibitors (C1/5) group comprises of very large number of herbicidal active ingredients and Terbuthylazine is just one active substance out of 25. In spite of significant resistance of weeds to herbicides representing photosystem II inhibitors group only 5 weed species and 6 cases were found to develop resistance directly to Terbuthylazine. There is no report documenting weeds species resistant to Terbuthylazine from Poland. Triazine resistance has been reported in several weed species worldwide, affecting crops where these herbicides are frequently used. Resistance can result in the need for higher doses or alternative weed management strategies.

Factors contributing to resistance: continuous and heavy reliance on terbuthylazine can select for resistant individuals within a weed population. Growing the same crops year after year can help resistant weeds to thrive and dominate.

Management strategies: Using herbicides with different modes of action can help prevent the development of resistance. Combining chemical, cultural and mechanical control methods. Regularly monitoring fields for signs of resistance and mapping resistant weed populations. Overall, while terbuthylazine is effective, prudent management and strategic use are critical to minimizing the risk of resistance development in weed populations.

The Applicant has provided a resistance risk assessment according to the standard: EPPO PP1 PP 1/213 (4) *resistance risk analysis*. Weeds are one of the most important reducing factors for crop yield reduction.

Terbuthylazine is a group code HRAC Group 5 (Legacy C1 herbicide (triazine)). Any weed population may contain individual weeds naturally resistant to terbuthylazine and other group code 5 herbicides. Resistance of *Amaranthus hybridus* to the chemical family of triazine has been observed in South Africa and Europe (ex. Czech Republic). If a triazine treatment has been ineffective in the control of the above-mentioned weeds, do not retreat with a herbicide from the same chemical group. Resistant individuals can eventually dominate the weed population if these herbicides are used repeatedly. Resistant weeds may not be controlled by terbuthylazine or any other group code 5 herbicide. In line to weed.science.org, six cases of resistance against terbuthylazine were noted. Four cases were noted in Czech Republic (*Polygonum lapathifolium*, *Amaranthus retroflexus*, *Chenopodium album* and *Senecio vulgaris*), one case in Italy (*Amaranthus retroflexus*) and one in New Zealand (*Solanum nigrum*). The probability of development of resistance or cross-resistance of weeds to terbuthylazine in EU and PL can be considered as a moderately high. The evaluation of the agronomic risk concludes that terbuthylazine bears a moderately to high risk of resistance in the EU.

The abundance of the requirements within the good agricultural practices is necessary. The resistance management is coordinated by HRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label. ZRMs accepted the resistance strategy form label of Terbutylazyna 500 SC proposed by Applicant:

Resistance Management Strategy:

To reduce the risk of herbicide resistance in weeds, Best Agricultural Practices recommend:

- strictly following the product label for the correct dosage and timing for optimal weed control.
- adjusting herbicide selection and application timing based on dominant weed species and infestation thresholds.
- rotating herbicides with different modes of action.
- using herbicide mixtures with diverse action mechanisms.

- applying herbicides with multiple action pathways.
- limiting a herbicide's use to once per growing season.
- adapting tillage to field and weed conditions.

integrating crop rotation and certified seeds, cleaning equipment, reporting control failures, and consulting authorized advisors for guidance.

3.3.2 Adverse effects on treated crops

Phytotoxicity effect:

Terbuthylazine, when applied to maize, can exhibit phytotoxicity effects under certain conditions. Phytotoxicity refers to the toxic effect a chemical substance can have on plants, which may manifest as growth inhibition, chlorosis, necrosis or even plant death. Over-application or incorrect dosage can increase the likelihood of phytotoxicity. Soil type, pH, and organic matter content can influence the herbicide's availability and hence its phytotoxic potential. Weather patterns, specifically temperature and rainfall, can affect how maize plants absorb and metabolize the herbicide. Understanding the factors that influence terbuthylazine's phytotoxic effects can help in managing its application and minimizing any adverse impacts on maize crops.

In the evaluation process the fact that the active ingredient – terbuthylazine is used in many plant protection products and has been commonly used in crop protection for many years were taken into consideration. The Applicant submitted in total 5 selectivity trials conducted on herbicide (Terbutylazyna 500 SC) containing this active substance. The selectivity evaluation of the herbicide was performed according to appropriate EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicide treatment compared to plant for unwanted, where 0% means no phytotoxicity and 100% - complete destruction. Phytotoxicity assessment was carried out with the use of different cultivars of maize. Dosages N (1,5 L/ha) and 2N (3,0 L/ha) for Terbutylazyna 500 SC and dose N (1,0 L/ha) and 2N (2,0 L/ha) for st. ref. product (Tezosar 500 SC) were studied in 5 selectivity trials carried out in PL (N-E EPPO zone) in 2022. All treatments were sprayed broadcast foliar at spray volume 300 L/ha using a backpack boom sprayer (3.0 m boom length with 6 flat fan nozzles) pre-emergence (A) of the crop and post-emergence (B) of the crop. No problems were encountered during mixing or application of the treatments. Experimental details and assessment methods were in accordance to EPPO standards. Results were comparable to standard reference products.

Overall summary of maize vigor in all selectivity trials conducted in maize where Terbuthylazine 500 SC was applied pre- and post-emergence:

| Levels of phytotoxicity | Terbutylazyna 500 SC | | TEZOSAR 500 S.C. | |
|-------------------------|----------------------|--------------------|-------------------|--------------------|
| | 1,5 L/ha (N dose) | 3,0 L/ha (2N dose) | 1,0 L/ha (N dose) | 2,0 L/ha (2N dose) |
| 0% | 5 | 5 | 5 | 5 |
| 0.1-5% | 0 | 0 | 0 | 0 |
| >5-10% | 0 | 0 | 0 | 0 |
| >10-15% | 0 | 0 | 0 | 0 |
| >15% | 0 | 0 | 0 | 0 |

No phytotoxicity symptoms were observed for any tested dosage for all tested maize varieties. The crop developed normally and did not involve a loss in yield at harvest.

Also, phytotoxicity effects of Terbutylazyna 500 SC were assessed during 8 efficacy trials. No phytotoxicity effect was observed in any trial for recommended doses: 1,0 L/ha and 1,5 L/ha. Results were compared to st. ref. product.

In briefly summary, it can be stated that Terbutylazyna 500 SC is safe for maize crops at recommended doses (1,0 L/ha and 1,5 L/ha) when is used in line to label recommendations.

Effect on the yield:

Terbuthylazine is effective in controlling a wide range of weed species, which can improve maize yield by reducing competition for nutrients, water and sunlight. When used correctly and under optimal conditions, terbuthylazine can help increase maize yield by effectively controlling weeds. However, careful management is required to avoid negative outcomes that may arise from its phytotoxic potential. It is crucial for

users to adhere to recommended application guidelines and consider environmental and soil conditions to maximize the positive impacts on maize yield.

Applicant submitted in total 5 selectivity trials carried out on maize in Poland in 2022. To evaluate the selectivity of Terbutylazyna 500 SC when applied pre-emergence and post-emergence in maize. Submitted trials are sufficient in the opinion of ZRMs. Those evaluation was carried out in line to EPPO guideline. In all trials no detrimental effect on the yield was recorded at the proposed dose rate and even at the double dose rate. Application of Terbutylazyna 500 SC provided a yield similar to the untreated plots and to those treated with the reference product. No statistical differences were observed between untreated and treated plots and also between the tested product and the standard product.

Effect on the quality of yield:

The quality of maize yield treated with terbuthylazine herbicide can be influenced in several ways, largely dependent on application practices and environmental conditions. The proper and regulated use of terbuthylazine can significantly benefit the quality of maize yield by promoting healthier plant growth and reducing weed-related competition. However, careful management is necessary to prevent any adverse effects that might arise from overuse or misuse, ensuring the quality of maize remain high.

Applicant submitted in total 5 selectivity trials carried out on maize in Poland in 2022. To evaluate the selectivity of Terbutylazyna 500 SC when applied pre-emergence and post-emergence in maize. Submitted trials are sufficient in the opinion of ZRMs. Those evaluation was carried out in line to EPPO guideline. Submitted trials are sufficient in the opinion of ZRMs. Impact of Terbutylazyna 500 SC on quantity and quality of yield was evaluated during selectivity trials. Following parameters were studied: moisture, TGW and HLW. In all trials no detrimental effect on the quality of yield was recorded at the proposed dose rate and even at the double dose rate. Application of Terbutylazyna 500 SC provided a quality yield similar to the untreated plots and to those treated with the reference product. No statistical differences were observed between untreated and treated plots and also between the tested product and the standard product.

3.3.3 Observations on other undesirable or unintended side-effects

No new data was submitted in the framework of this application.

Effect on the transformation processes:

Maize treated with Terbuthylazine may influence transformation processes such as silage production, bio-fuel generation and alcohol fermentation.

Silage production: Terbuthylazine residues can affect the microbial flora responsible for fermentation in silage production. It is essential to monitor residue levels to avoid negative impacts on fermentation efficiency and to ensure nutritional value is maintained.

Biofuel production: residues might interfere with microorganisms, compromising ethanol yields. Ensuring low residue levels can help maintain efficient fermentation. Terbuthylazine might also impact anaerobic digestion processes used in biogas production, as chemical residues could inhibit microbial activity needed for effective gas yield.

Alcohol production: Terbuthylazine residues could hinder yeast activity, prolonging fermentation time or reducing alcohol yield. Proper residue management ensures effective fermentation.

Strict adherence to herbicide application guidelines is crucial to minimize residues. While Terbuthylazine treated maize can be still utilized in the production of silage, biofuels and alcohol, careful management of herbicide residues is critical to ensure these processes are efficient and yield high quality products.

In the opinion of ZRMs, considering that product is applied pre-emergence (BBCH 00) or early post-emergence (BBCH 12-16) of the crop and maize is not a typical crop used for subsequent processing, it could be agreed that no negative impact on processing is expected.

Effect on the propagating purposes:

Terbutylazyna 500 SC is a basically soil-applied, pre-emergence or early post-emergence of herbicide of which decomposes in plants to non-toxic metabolites during the vegetation period. Information's about residues should be presented in the Residue Section.

The active substance: Terbutylazine, is commonly used for many years in many countries. No adverse effects on parts of plant used for propagating purposes were reported. Therefore, it can be assumed that application of Terbutylazyna 500 SC in maize will pose no risk for maize propagation capabilities.

Impact on the succeeding crops:

The effects of Terbutylazine on succeeding crops largely depends on factors such as soil type, environmental conditions, timing of application and subsequent crop selections. Implementing careful management can help mitigate adverse effects while benefiting from its weed control properties.

The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops. Therefore, the Applicant should present the assessment of the possible effect of Terbutylazyna 500 SC on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance to the EPPO Standard Efficacy evaluation of plant protection products.

Effects on succeeding crops (PP 1/207(2)). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops grown after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.

Applicant did not present any results and information's about impact on the succeeding crops. The half-life (DT₅₀) for Terbutylazine is 77-169 days. Product decomposes in the soil during the growing season without endangering crops. Therefore, it can be assumed that application of Terbutylazyna 500 SC in maize will pose no risk for succeeding crops. As regards effects on succeeding crops the applicant proposed the following label text which was accepted by ZRMs.

Necessary precautions to prevent the negative impact on succeeding crops should be included in the label claim: *"The PPP decomposes in the soil during the growing season to a level that does not pose a risk to subsequent crops. In the event of an early termination of the treated crops (due to plant damage from frost, diseases or pests), only corn can be cultivated after pre-sowing tillage"*.

Impact on the adjacent crops:

The application of Terbutylazine herbicide in maize cultivation can significantly impact adjacent crops. During application, Terbutylazine can drift to nearby fields, potentially harming adjacent crops that are more sensitive to the herbicide. Terbutylazine can leach into neighbouring areas through soil movement or runoff, leading to residual herbicide affecting the germination and growth of nearby crops.

To minimize negative impact on adjacent crops, should be consider:

- buffer zones: for protecting adjacent fields from drift and residue
- application timings: use at optimal weather conditions for application to reduce the risk of drift to nearby crops.

Proper management practices are essential to safe guard neighbouring crops while still benefiting from the herbicide's effectiveness in weed control.

Generally, the product is a foliar herbicide effective on broadleaf weeds. Therefore, warning to avoid spray drift on adjacent crops should appear on the label. Terbutylazyna 500 SC effectively control broadleaf weeds therefore users must exercise caution to avoid drift or vapours which may cause stunting or discoloration and damage to non-target foliage.

Detailed assessment of predicted rates of Terbutylazyna 500 SC in off-field areas, the TER values describing the risk for non-target plants should be described in Ecotoxicological sections.

Impact on beneficial and non-target organisms:

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in part B of Ecotoxicology Section.

The impact of terbutylazine herbicide on beneficial and non-target organisms is a significant concern in agricultural practices. Exposure to terbutylazine may lead to reduced earthworm populations. While ter-

buthylazine is not typically directly applied to flowering plants, drift or runoff can affect pollinator populations, such as bees. If terbuthylazine enters water bodies through runoff, it can harm aquatic organisms, including fish and amphibians.

To protect beneficial and non-target organisms, consider implementing the following strategies:

- *Integrated Pest Management*: use biological control agents and cultural practices alongside herbicides to maintain ecological balance.
- *Targeted application*: apply terbuthylazine in a manner that minimizes exposure to non-target organisms, such as applying during calm weather to reduce drift.

Buffer zones: create buffer zones around sensitive habitats to protect beneficial organisms from herbicide exposure.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for determination of terbuthylazine in product H-01-2022 was not evaluated as part of the EU review of this active substance. Therefore, all relevant data are provided and are considered adequate.

The determination of terbuthylazine was performed after dilution with acetonitrile by HPLC analysis with DAD detection. The range of linearity of the analytical graph, selectivity and specificity, precision and accuracy were determined. The method was fully validated according to SANCO 3030/99 rev.5 and assure appropriate active substances determination in the formulation H-01-2022.

| Analytical Validation Criteria | Results for terbuthylazine | Acceptability according to SANCO 3030/99 rev. 5 |
|--------------------------------|----------------------------|---|
| Specificity | No interference | Interference <3% of analyte |
| Correlation coefficient | $r^2 = 0.9993$ | $r^2 \geq 0.98$ |
| Precision (Horrat) | 0.33 | Horrat ≤ 1 |
| Accuracy | 101.5 % | 90-110 % |

The determination of relevant impurities (atrazine, propazine, simazine) was performed by HPLC-DAD method. This method was also fully validated according to SANCO 3030/99 rev.5 and assure appropriate relevant impurities determination in the formulation H-01-2022.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions for terbuthylazine. All analytical methods are active substances data and were provided in the EU review of terbuthylazine and were considered adequate.

| Commodity/crop | Supported/ Not supported |
|----------------|-----------------------------|
| Maize (seeds) | Supported |

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

No acute toxicity studies were performed for product H-01-2022. The classification of product is based on the composition of the product and was performed according to the Regulation (EC) of the European Parliament and of the Council No. 1272/2008 of December 16th, 2008, *on classification, labelling and packaging of substances and mixtures*. Details on composition and classification of formulants are provided in dRR Part C.

| Hazard categories with regard to toxicological data | Product classification |
|--|---|
| Acute oral toxicity | Acute Tox. 4, H302 |
| Acute dermal toxicity | According to Regulation (EC) No. 1272/2008 no classification is required. |
| Acute inhalation toxicity | According to Regulation (EC) No. 1272/2008 no classification is required. |
| Skin Irritation | According to Regulation (EC) No. 1272/2008 no classification is required. |
| Eye Irritation | Eye Irrit. 2, H319 |
| Skin sensitisation | Skin Sens. 1, H317 |
| Specific target organ toxicity - repeated exposure | STOT RE 2, H373 |

3.5.2 Operator exposure

The operator exposure was assessed against the AOELs for terbuthylazine (EFSA Journal 2011; 9(1):1969). Proposed dermal absorption rates used for the calculations are based on dermal absorption study on a formulation H-01-2022.

Operator exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.).

According to the model calculations, it can be concluded that the risk for the operator using H-01-2022 on intended uses presented in GAP table is acceptable if operator is equipped with work wear (arms, body and legs covered) and protective gloves during mixing/loading.

3.5.3 Worker exposure

The worker exposure was assessed against the AOELs for terbuthylazine (EFSA Journal 2011; 9(1):1969). Proposed dermal absorption rates used for the calculations are based on dermal absorption study on a formulation H-01-2022.

Worker exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.).

The results of the exposure estimations show that the use of H-01-2022 according to the list of intended uses presented in GAP Table, causes no health risk for the worker if the workwear (arms, body and legs covered) is used. The calculated exposure level to terbuthylazine is lower than the value of AOEL for this active substance.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.5.4 Bystander and resident exposure

The bystander/resident exposure was assessed against the AOELs for terbuthylazine (EFSA Journal 2011; 9(1):1969). Proposed dermal absorption rates used for the calculations are based on dermal absorption study on a formulation H-01-2022.

Bystander/resident exposure were modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.) and German bystander and resident model.

The reference value acutely toxic active substance (RVAAS) for terbuthylazine is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards this active substance.

The long-term exposure of residents (children) to terbuthylazine via re-entry and the sum of all pathways, calculated with the EFSA calculator, was estimated to be slightly above the systemic AOEL for this active substance. Calculation performed with additional model (German bystander and resident model) shows no exceedance of AOEL for terbuthylazine.

Taking into account above, an additional risk mitigation measures should be included on the label:

- “After the application of product, place warning boards in visible places around the field: "No unauthorized access to the area treated with plant protection products ". The boards should remain until the plants are harvested.”
- “During spraying, a protection zone of at least 5 m away from residential buildings/habitats and bystanders should be used.”
- “During spraying, appropriate techniques to reduce product drift (anti-drift nozzles) should be used.”

It can be concluded that the incidental short-time exposure of bystander and resident (children and adult) to terbuthylazine contained in the formulation H-01-2022 causes no risk to human health if the product is used in accordance with the intended uses listed in the GAP Table and using above risk mitigation measures.

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

Stability of residues

According to EFSA, 2011, residues of terbuthylazine and its metabolites in cereal samples are considered to be stable at least for 24 months at -18°C.

Metabolism

All metabolism data are active substance data and were evaluated in the EU review. The intended uses are covered by the available metabolism studies reported in the EU.

Plant residue definition for monitoring Terbutylazine (MT0) (EFSA, 2011, 2020; Reg. (EU) 2021/1795)

Plant residue definition for risk assessment Sum terbutylazine (MT0), desethyl-terbutylazine (MT1) and desethyl-hydroxy-terbutylazine (MT14) (EFSA, 2011, 2017, 2020)

Conversion factor from enforcement to RA Not necessary for maize grains (all residue data <LOQ) (EFSA 2011,2020)

Animal residue definition for monitoring and risk assessment (EFSA Journal 2020;18(1):59800):

Ruminants

Milk: Sum of terbutylazine and MT1, expressed as terbutylazine

Muscle, fat, liver and kidney: open

Pigs: not triggered; Poultry: not triggered

Magnitude of residues in plants

Proposed GAP: maize, 1 application, BBCH 00 and 12-16); Application rate per treatment: 500-750 g as/ha.

Targeted range: 1.0-1.5 L/ha every 3 years

Maize is a major crop in Northern Europe. Therefore, 8 NEU trials are required to support the proposed use.

GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, , pre-emergence and BBCH 12-16 PHI is not relevant, outdoor

No new data are submitted in the framework of this application.

Applicant refers to EU unprotected trials results:

E (mg/kg): 8 X <0.02 mg/kg

RA (mg/kg):

MT0: 8x <0.02

MT1: 8x <0.02

MT14: 8x <0.02

Total residues: 8x <0.06 mg/kg

Forage (mg/kg):

MT0: 8x <0.02

MT1: 8x <0.02

MT14: 7x <0.02, 0.03

Total residues: 7x <0.06, 0.07 mg/kg

The data submitted show that no exceedance of the MRL will occur (Reg. (EU) 2021/1795).

Uses are acceptable

Magnitude of residues in livestock

The data evaluated during the Annex I inclusion of terbutylazine are considered sufficient. No further studies are required.

Processing studies

EFSA Journal 2020;18(1):5980: *Standard hydrolysis studies are not available and were not considered necessary because residues of terbutylazine in primary crops were below limit of quantification (LOQ).*

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No further studies have been performed

Magnitude of residues in representative succeeding crops

EFSA Journal 2020;18(1):5980: *Residues in following crops are expected to be low. However, residues of MT1 and MT14 above the LOQ occur in sunflower seeds, rape seeds, sugar beet tops and cereal straw however not at PBIs above 1 year.*

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).

Other / special studies

Studies are not required for maize.

Estimation of exposure through diet and other means

The proposed uses of terbuthylazine in the formulation H-01-2022 does not represent unacceptable chronic and acute risks for the consumer.

Note: Use restricted to once every third year on the same field at a maximum rate of 850 g/ha (Terbuthylazine, SANCO/11337/2011 rev 3, 17 June 2011, 24 March 2021; Commission Implementing Regulation (EU) 2021/824 of 21 May 2021).

3.6.2 Consumer exposure

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1) provided on the internet homepage of EFSA (<https://www.efsa.europa.eu/>). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

| | |
|--|--|
| ADI | 0.004 mg/kg bw/day |
| TMDI (% ADI) according to EFSA PRIMo rev. 3.1 | 55% (based on NL toddler diet) |
| IEDI (% ADI) according to EFSA PRIMo rev. 3.1 | Not relevant. TMDI < 100%. |
| ARfD | 0.008 mg/kg bw |
| IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 | <u>Unprocessed commodities - children</u> 5% Maize/corn (based on UK infant diet) <u>Unprocessed commodities - adults</u> 2% Maize/corn (based on FI men diet) <u>Processed commodities - children</u> 17% Maize/oil (based on NL toddler diet) 2% Maize/processed (not specified) (based on NL toddler diet) <u>Processed commodities - adults</u> 10% Maize/oil (based on NL general population) |

The proposed uses of terbuthylazine in the formulation H-01-2022 does not represent unacceptable chronic and acute risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} modelling for terbuthylazine and its metabolites MT1 and MT13 was performed with Excel calculator based on simple equations included in FOCUS guidance – FOCUS (1997): Soil persistence models and EU registration. PEC_{soil} for formulation was obtained from PEC_{soil} for active substance taking into account content of active substance and density of the formulation. The obtained PEC_{soil} values were used in further risk assessment. The metabolite desethy-hydroxy-terbuthylazine (MT14) is considered to be a minor metabolite, present at only 1.9% AR so PEC_{soil} was not calculated.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} for terbuthylazine and its metabolites MT1, MT13, MT14, LM1, LM2, LM3, LM4, LM5, LM6 after application to maize were calculated with PELMO 6.6.4, PEARL 5.5.5 and MACRO 5.5.4. In accordance with 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. Use of terbuthylazine shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.

PEC_{gw} for the active substance and metabolite LM1 are below the trigger value of 0.1 µg/L. There is no unacceptable risk of groundwater contamination with those molecules. PEC_{gw} are above the trigger value of 0.1 µg/L and in most cases above the trigger value of 0.75 µg/L. Further evaluation of metabolites relevance was performed in dRR Part B Section 10.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

PEC_{sw} for terbuthylazine and its metabolites MT1, MT13, MT14 and MT26 after application to maize were calculated with FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v.5.0.1. PEC_{sw} values were used in aquatic risk assessment.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The fate and behaviour of terbuthylazine in air was evaluated during the EU review. The active substance terbuthylazine has a vapour pressure of 9.0×10^{-5} Pa m³/mol at 25 °C and could be considered volatile. Volatilization of terbuthylazine from plant was ≤ 10.2 % after 24 hours and from soil ≤ 13.8 % after 24 hours. However due to rapid photochemical degradation, exposure of adjacent surface waters and terrestrial ecosystems by the terbuthylazine due to volatilization with subsequent deposition is not considered. Terbuthylazine does not need to be assessed for long range transport due to low DT₅₀ in air.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

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.

Terrestrial vertebrates (other than birds)

Uses are accepted 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. The refinement risk assessment for mammals should be considered by MSs level. The refinement risk assessment for mammals was corrected by zRMS. According to both EFSA 2009 and EFSA 2023 as well as the zonal agreements, interception cannot be considered in early stages. Also for the use of pre-emergence application and post- emergence exposure, interception should not be used. The TER for maximum dose rate 750 g s.s./ha is slightly below trigger value 5 (4.97). In opinion this TER should be accepted. The further risk assessment is not needed. The refinement risk assessment for mammals should be considered by MSs level.

3.8.2 Effects on aquatic species

Effects on aquatic organisms for H-01-2022 were not evaluated as part of the EU review of terbuthylazine. The studies on effects of H-01-2022 on algae, *Daphnia magna* and aquatic plants were submitted in this dossier and deemed acceptable for evaluation and authorisation of H-01-2022.

Risk assessments for H-01-2022 with the proposed use pattern was carried out according to the latest guidance for risk assessment for aquatic organisms in edge-of-field surface water EFSA Journal 2013; 11(7):3290.

PEC/RAC values were calculated on the basis of PEC_{sw} calculations as well as worst case toxicity endpoints from studies for active substance, metabolites and formulation H-01-2022. PEC_{sw} Step 3/RAC values for active substance were less than 1 for few scenarios so further evaluation with Step 4 PEC_{sw} was performed. On the basis of PEC/RAC values it was concluded that the application of H-01-2022 does not pose unacceptable risk for aquatic organisms under condition that appropriate risk mitigations are applied.

For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that H-01-2022 used to protect maize according to proposed GAP does not pose unacceptable risk to aquatic organisms under condition that: 5m vegetated buffer zone is applied.

Classification of H-01-2022 was done on the basis of formulation H-01-2022 studies' results as well as active substance and co-formulants properties. The proposed classification of the product H-01-2022 is:

Aquatic Acute 1, H400
Aquatic Chronic 1, H410

Based on the results with consideration FOCUS STEP 4 for scenarios relevant for Poland the following risk mitigation are required:

-5m buffer non-spray zone with 5 meter vegetated filter strip to surface water bodies

Final risk mitigation measures should be considered at MSs level.

3.8.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The required study on oral and contact toxicity of the formulated product H-01-2022 to honeybees was conducted and considered to be valid. The endpoints as proposed by the Notifier are considered acceptable and are used in the risk assessment. All hazard quotients for acute oral and acute contact exposure were below 50, the Commission Regulation (EU) No. 546/2011 criterion, indicating low risk to honey bees. The chronic studies with formulation H-01-2022 were submitted. The studies were accepted by zRMS. The risk assessment based on these studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.

3.8.4 Effects on other arthropod species other than bees

Effects on non-target arthropods for H-01-2022 were not evaluated as part of the EU review of terbutylazine. The studies on effects of H-01-2022 on arthropods were submitted in this dossier and deemed acceptable for evaluation and authorisation of H-01-2022.

Risk assessments for H-01-2022 with the proposed use pattern was carried out according to the guidance for risk assessment for arthropods “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and in consideration of the recommendations of the guidance document ESCORT 2.

The in-field and off-field risk of H-01-2022 to non-target arthropods was assessed from Hazard Quotients (HQ) between toxicity endpoints estimated from studies with the formulated product H-01-2022 as well as in-field and off-field predicted environmental rate. No risk was determined in-field and off-field after application of H-01-2022 according to proposed GAP. No risk management measures are required.

3.8.5 Effects on soil organisms

Effects on earthworms and other soil micro-organisms for H-01-2022 were not evaluated as part of the EU review of terbutylazine. The studies on effects of H-01-2022 on earthworms and other micro and macro-organisms were submitted in this dossier and deemed acceptable for evaluation and authorisation of H-01-2022.

Risk assessments for H-01-2022 with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

Earthworms

The risk of H-01-2022 to earthworms was assessed from toxicity exposure ratios (TERs) between the selected toxicity endpoints for metabolites and the formulated product H-01-2022 as well as the maximum soil PECs.

The chronic TER values were greater than the trigger of 5 indicating an acceptable risk to earthworms following application of H-01-2022 according to proposed GAP. No risk management measures are required.

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.

Folsomia candida and Hypoaspis aculeifer

The risk of H-01-2022 to *Folsomia candida* and *Hypoaspis aculeifer* was assessed from toxicity exposure ratios (TERs) between the endpoint for the formulated product H-01-2022 as well as the maximum soil PECs.

The acute and chronic TER values were greater than the trigger of 5 indicating an acceptable risk to *Folsomia candida* and *Hypoaspis aculeifer* following application of H-01-2022 according to proposed GAP. No risk management measures are required.

Micro-organisms

The risk of H-01-2022 to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for active substance, metabolites and the formulated product H-01-2022 with predicted application concentrations (PECs).

Considering to the performed risk assessment it was assessed that the application of H-01-2022 according to proposed GAP does not pose unacceptable risk to soil micro-organisms. No risk management measures are required.

3.8.6 Effects on non-target terrestrial plants

Effects on non-target terrestrial plants for H-01-2022 were not evaluated as part of the EU review of terbutylazine. The studies on seedling emergence and vegetative vigour for H-01-2022 were submitted in this dossier and deemed acceptable for evaluation and authorisation of H-01-2022.

The risk of H-01-2022 to non-target plants was assessed from toxicity exposure ratios between toxicity endpoints for the formulation H-01-2022 and off-field predicted environmental rate.

The risk of H-01-2022 to non-target plants was evaluated by comparison of toxicity endpoints derived from laboratory tests for the formulation H-01-2022 with application rates. According to the performed risk assessment it was assessed that the application of H-01-2022 at maximum rate of 1.5 L/ha (750 g as/ha) does not pose unacceptable risk to non-target plants provided risk mitigation measures are applied:

- 5m buffer zone or
- 50% nozzle reduction.

In case of lower application rate 1 L/ha no risk mitigation measures are required.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

PEC_{gw} values for metabolites MT1, MT13, MT14, LM2, LM3, LM4, LM5 and LM6 were above 0.1 µg/L for most scenarios and for some scenarios also above 0.75 µg/L. However, on the basis of toxicological assessment according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10, those metabolites are not relevant.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Product H-01-2022 contains terbuthylazine as active substance which is not approved as a candidate for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

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)

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Not relevant.

Appendix 2 Copy of the product label

Sekcja skuteczność: Dodano, że środek może być stosowany na kukurydzy uprawianej na ziarno, kiszonkę i bioetanol. Zmieniono listę zaakceptowanych gatunków chwastów i skalę ich wrażliwości. Rekomendowana ilość wody to 150-300 L/ha. Pozostałych zapisów etykiety nie zmieniano.

Sekcja Pozostałości:

Zmieniono akapit: następstwo roślin.

Zalecane środki ograniczające ryzyko dla upraw następnych (jedna z dwóch opcji do rozważenia przez aplikanta): roczna przerwa między sadzeniem roślin lub głęboka orka (mieszanie gleby po-wyżej 20 cm) w celu rozcieńczenia stężeń gleby, przy czym należy zauważyć, że głębokość orki wynosząca 30 cm zmniejsza pozostałości gleby o współczynnik 1,5, a głębokość orki wynosząca 40 cm na 50%. (według EFSA Journal 2020; 18 (1): 5980).

W przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) roczna przerwa między sadzeniem roślin innych niż kukurydza. Kukurydzę można uprawiać w tym samym sezonie pod warunkiem nie zastosowania w ochronie tej uprawy środka ochrony roślin zawierającego terbutyloazynę..

Sekcja losu:

Do etykiety środka dodano następujące ograniczenie:

„W celu ochrony wód podziemnych środek powinien być stosowany raz na trzy lata na tej samej powierzchni”.

Sekcja ekotoksykologii:

Zastosowania są zaakceptowane do maksymalnej dawki 500 g s.a./ha.

W celu ochrony wód podziemnych środek powinien być stosowany raz na trzy lata, na tej samej powierzchni.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 5 metrów od zbiorników i cieków wodnych.

W celu ochrony roślin i stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości:

- 5 metrów lub,
- 1 metr z równoczesnym zastosowaniem odpowiednich końcówek do rozpylaczy redukujących znoszenie cieczy użytkowej o 50%.

Posiadacz zezwolenia:

ProAgri International Sp. z o.o., ul. Dziekońskiego 1, 00-728 Warszawa, Polska, tel.: +48 71 314 64 54, e-mail: contact@proagri.com, www.proagri.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

ProAgri sp. z o.o., ul. Kolejowa 6, 56-420 Bierutów, Polska, tel.: +48 71 314 64 54, e-mail: contact@proagri.com


TERBUTYLAZYNA 500 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

terbutyloazyna (terbutylazyna) (związek z grupy triazyn) - 500 g/l (44,88 %)

Zezwolenie MRiRW nr R- /2024 z dnia .2024 r.

| | |
|---|--|
|  | |
| Uwaga | |
| H302 H317 H319 H373 H410 | <p>Działa szkodliwie po połknięciu.</p> <p>Może powodować reakcję alergiczną skóry.</p> <p>Działa drażniąco na oczy.</p> <p>Może powodować uszkodzenie narządów poprzez długotrwałe lub narażenie powtarzane.</p> <p>Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.</p> |
| EUH401 | W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia. |
| P260 P264 P270 P280 P301 + P312 P302 + P352 P305 + P351 + P338 P333 + P313 P337+P313 P362+P364 P314 P391 | <p>Nie wdychać mgły, par, rozpylonej cieczy.</p> <p>Dokładnie umyć ręce po użyciu.</p> <p>Nie jeść, nie pić i nie palić podczas używania produktu</p> <p>Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.</p> <p>PRZYPADKU POŁKNIECIA: w przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.</p> <p>W PRZYPADKU DOSTANIA SIĘ NA SKÓRĘ: Umyć dużą ilością wody /mydłem.</p> <p>W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.</p> <p>W przypadku podrażnienia skóry lub wysypki: Zgłosić się pod opiekę lekarza.</p> <p>W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.</p> <p>Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.</p> <p>W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza</p> <p>Zebrać wyciek.</p> |

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany dogłębowo. Koncentrat w postaci stężonej zawiesiny do rozcieńczania z wodą (SC).

Zgodnie z klasyfikacją HRAC substancja czynna terbutyloazyna należy do grupy 5.

DZIAŁANIE NA CHWASTY

Środek pobierany jest głównie poprzez korzenie chwastów i w niewielkim stopniu poprzez ich liście, powoduje zakłócenia w procesie fotosyntezy, wywołując w pierwszej kolejności chlorozy liści widoczne w szczególności w przestrzeniach międzynerwowych, a także na brzegach i wierzchołkach. Niszczy chwasty od fazy kiełkowania do fazy 4 liści. Środek ogranicza wschody chwastów przez 6-8 tygodni po wykonaniu zabiegu.

Umiarkowane opady i ciepła pogoda sprzyjają działaniu środka.

Zastosowanie przed wschodami kukurydzy (BBCH 00)**dawka 1,0 i ~~1,5~~ L/ha**

| | |
|---------------------------------|--|
| Chwasty wrażliwe: | chaber bławatek, gwiazdnica pospolita, fiołek polny (średnio wrażliwy w dawce 1,0 L/ha), komosa biała, maruna bezwonna (średnio wrażliwa w dawce 1,0 L/ha) , przetacznik bluszczykowy, przytulia czepna, psianka czarna, rdestówka powojowata (rdest powojowaty), szarłat szorstki , tasznik pospolity, żóltlica drobnokwiatowa, gorczyca polna, tobołki polne |
| Chwasty średnio wrażliwe | fiołek polny, maruna bezwonna |

Zastosowanie od fazy 2 liści do fazy 6 liści kukurydzy (BBCH 12-16).**dawka 1,0 i ~~1,5~~ L/ha**

| | |
|--------------------------------|--|
| Chwasty wrażliwe: | chaber bławatek, gwiazdnica pospolita, przetacznik bluszczykowy, przytulia czepna, tasznik pospolity, żóltlica drobnokwiatowa, gorczyca polna, tobołki polne |
| Chwasty średniowrażliwe | maruna bezwonna, fiołek polny |

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Kukurydza uprawiana na ziarno, kiszonkę i bioetanol

Maksymalna dawka dla jednorazowego zastosowania: ~~1,5 l/ha~~ 1,0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 1,0 ~~– 1,5~~ l/ha.

Termin stosowania:

a) Przed wschodami kukurydzy (BBCH 00)

lub

b) Od fazy 2 liści do fazy 6 liści kukurydzy (BBCH 12-16).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: ~~100-400~~ 150-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
nie wymagany

1. Strategia zarządzania odpornością.

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecany terminie zapewniającym optymalne zwalczanie chwastów,
- dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,

- stosować mieszanek herbicydów (substancji czynnych) o różnym mechanizmie działania,
 - stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
 - stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
 - dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
 - używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
 - używać kwalifikowanego materiału siewnego,
 - czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
 - informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
 - w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.
2. Środka nie należy stosować na stanowiskach, gdzie występują biotypy chwastów o potwierdzonej odporności na substancje czynne zaliczane zgodnie z klasyfikacją HRAC do grupy 5.
 3. Nie zaleca się stosowania środka w liniach wsobnych kukurydzy i na plantacjach nasiennych bez uprzedniego wykonania próbnego zabiegu w celu sprawdzenia, czy nie występują objawy uszkodzenia roślin lub bez skontaktowania się z doradcą albo przedstawicielem posiadacza zezwolenia.
 4. W niesprzyjających warunkach pogodowych (np. susza, przymrozki, duże wahania temperatur pomiędzy nocą i dniem), środek może spowodować na niektórych odmianach kukurydzy, przemijające uszkodzenia liści, które nie mają negatywnego wpływu na jakość i wielkość plonu.
 5. Środka nie stosować:
 - w kukurydzy cukrowej,
 - na rośliny słabe lub uszkodzone przez przymrozki, choroby lub szkodniki, mokre,
 - w czasie opadu deszczu lub przed spodziewanym deszczem,
 - w temperaturze (mierzonej przy gruncie) poniżej 12°C i powyżej 25°C,
 - w czasie południowych upałów i silnego nasłonecznienia,
 - po długotrwałej suszy,
 - na glebach bardzo przepuszczalnych.
 6. Podczas stosowania środka nie dopuścić do:
 - noszenia cieczy użytkowej na sąsiednie rośliny uprawne,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w glebie w ciągu okresu wegetacji do poziomu niestwarzającego zagrożenia dla roślin uprawianych następczo.

W przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) po wykonaniu uprawy przedsięwziętej można jedynie uprawiać kukurydzę.

Następstwo roślin:

Jedna z dwóch opcji do rozważenia przez aplikanta: roczna przerwa między sadzeniem roślin lub głęboka orka (mieszanie gleby powyżej 20 cm) w celu rozcięcia stężeń gleby, przy czym należy zauważyć, że głębokość orki wynosząca 30 cm zmniejsza pozostałości gleby o współczynnik 1,5, a głębokość orki wynosząca 40 cm na 50%.

Wcześniejsza likwidacja plantacji:

W przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki)-roczna przerwa między sadzeniem roślin innych niż kukurydza. Kukurydzę można uprawiać w tym samym sezonie pod warunkiem nie zastosowania w ochronie tej uprawy środka ochrony roślin zawierającego terbutyloazynę.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć oraz przepłukać co najmniej trzykrotnie wodą.

Niewystarczające wymycie aparatury po zabiegu i pozostawienie resztek środka w opryskiwaczu może być przyczyną silnych uszkodzeń roślin uprawnych wrażliwych na ten środek.

By uniknąć szkód dla upraw innych niż kukurydza, całe urządzenie opryskiwacza musi być zupełnie wyczyszczone od wewnątrz i na zewnątrz. Dlatego natychmiast po oprysku opróżnić zbiornik z cieczy.

Oplukać wnętrze zbiornika i przemyć czystą wodą wraz z węzami i dyszami. Każde zanieczyszczenie na zewnątrz opryskiwacza powinno być usunięte przez mycie czystą wodą.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon oraz odpowiednie obuwie np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Po wykonanym zabiegu umieścić w widocznych miejscach wokół pola tablice ostrzegawcze o brzmieniu „Zakaz wstępu osobom postronnym na teren poddany zabiegom środkami ochrony roślin”.

Tablice powinny pozostać do czasu zbioru roślin/końca sezonu wegetacyjnego.

W czasie oprysku należy zastosować co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.

W czasie oprysku należy zastosować techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe, mała prędkość pojazdu, stabilna pogoda i inne).

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg. Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony wód podziemnych środek powinien być stosowany raz na trzy lata, na tej samej powierzchni.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie **zadarnionej** strefy ochronnej o szerokości 5 metrów od zbiorników i cieków wodnych.

W celu ochrony roślin i stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości:

- 5 metrów lub,
- 1 metr z równoczesnym zastosowaniem odpowiednich końcówek do rozpylaczy redukujących znoszenie cieczy użytkowej o 50%.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C - 30°C,
- w pojemniku szczelnie zamkniętym.

Chronić przed mrozem.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W przypadku połknięcia: w przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc lub lekarzem.

W przypadku dostania się na skórę: Umyć dużą ilością wody/mydłem.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W przypadku podrażnienia skóry lub wysypki: Zgłosić się pod opiekę lekarza.

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza

Okres ważności - 2 lata
Data produkcji -
Zawartość netto -
Nr partii -

Appendix 3 Letter of Access

Letters of Access are submitted as separate annexes to this application.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|-------------------|------|---|-------------------------|--------------------------------|---|---------------------|
| KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11 | Condorelli A.M.M. | 2023 | Determination of the Physical-Chemical properties of H-01-2022 Product Before and after Accelerated Storage for 14 days at 54±2 °C and low temperature storage for 7 days at 0±2°C. Report No. 22363-02C Renolab S.r.l. GLP Published | N | Y | New study never submitted before to PL | ProAgri Sp. z o. o. |
| KCP 2.7.1 | Condorelli A.M.M. | 2025 | Amendment No. 1 Final Report 22363-02C. Determination of the Physical-Chemical properties of H-01-2022 Product Before and after Accelerated Storage for 14 days at 54±2 °C and low temperature storage for 7 days at 0±2°C. Renolab S.r.l. | N | Y | New study never submitted before to PL | ProAgri Sp. z o. o. |
| KCP 5.1.1/01 KCP 5.1.1/02 | Condorelli A.M.M. | 2023 | Analytical Method Validation for Active Ingredient and impurities Content Determination of the H-01-2022 product in Order to Provide an Analytical Certificate Report No. 22363-01C Renolab S.r.l. | N | Y | New study never submitted before to PL | ProAgri Sp. z o. o. |

H-01-2022

Part A - National Assessment

Version April 2024

Applicant version

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|--|----------------|------|--|-------------------------|--------------------------------|---|----------------------------------|
| | | | GLP Published | | | | |
| KCP 5.1.2/01 | Mautino G. | 2023 | Predatory mite <i>Hypoaspis (Geolaelaps) aculeifer</i> reproduction test in soil with H-01-2022 (terbuthylazine 500 g/L) - Analytical Phase Report No.: 1015.1H.SAG23 / 23133-01R Renolab S.r.l. GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/02 filed as KCP 10.5/01 | Kiran Yadav C. | 2023 | SOIL MICROORGANISMS: NITROGEN TRANSFORMATION TEST OF H-01-2022 Report No.: AG-G1155 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/03 (filed as KCP 10.2.1.2/01) | Likith N.G. | 2023 | H-01-2022: <i>Daphnia magna</i> , ACUTE IMMOBILIZATION TEST Report No.: AG-G1146 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/04 (filed as KCP 10.2.1.3/01) | Likith N.G. | 2023 | H-01-2022: ALGA GROWTH INHIBITION TEST WITH <i>Raphidocelis subcapitata</i> Report No.: AG-G1147 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/05 (filed as KCP 10.2.1.4/01) | Likith N.G. | 2023 | H-01-2022: <i>LEMNA</i> GROWTH INHIBITION TEST Report No.: AG-G1148 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |

H-01-2022

Part A - National Assessment

Version April 2024

Applicant version

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|--|-----------------|------|--|----------------------|-----------------------------|---|----------------------------------|
| KCP 5.1.2/06 (filed as KCP 10.4.1.1/01) | Vishala N. | 2023 | H-01-2022: EARTHWORM REPRODUCTION TEST (<i>Eisenia fetida</i>) Report No.: AG-G1153 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/07 (filed as KCP 10.2.1.4/02) | Likith N.G. | 2023 | H-01-2022: WATER SEDIMENT <i>MYRIOPHYLLUM SPICATUM</i> TOXICITY TEST Report No.: AG-G1158 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/08 (filed as KCP 10.3.1.4/01) | Gangadhar R. S. | 2024 | H-01-2022: HONEYBEE (<i>Apis mellifera</i> L) LARVAL TOXICITY TEST, REPEATED EXPOSURE Report No.: AG-G1149 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/09 (filed as KCP 10.3.1.1.2/02) | Gangadhar R. S. | 2024 | H-01-2022: CHRONIC ORAL TOXICITY TEST IN HONEYBEE (<i>Apis mellifera</i> L.) Report No.: AG-G1152 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/10 (filed as KCP 10.6.2/01) | Vishala N. | 2023 | H-01-2022: SEEDLING EMERGENCE AND SEEDLING GROWTH TEST WITH TERRESTRIAL PLANTS Report No.: AG-G1156 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 5.1.2/11 (filed as KCP 10.6.2/02) | Vishala N. | 2023 | H-01-2022: VEGETATIVE VIGOUR TEST Report No.: AG-G1157 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |

H-01-2022

Part A - National Assessment

Version April 2024

Applicant version

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|------------|------------------------|------|--|-------------------------|--------------------------------|---|--------------------|
| | | | PRIVATE LIMITED GLP Unpublished | | | | |
| KCP 6.2 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the efficacy of Terbutylazyna 500 SC against weeds in maize Report No.: 044GPSE202204 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/01 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the efficacy of Terbutylazyna 500 SC against weeds in maize Report No.: 044GPSE202201 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/02 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the efficacy of Terbutylazyna 500 SC against weeds in maize Report No.: 044GPSE202202 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/03 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the efficacy of Terbutylazyna 500 SC against weeds in maize Report No.: 044GPSE202203 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/05 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the efficacy of Terbutylazyna 500 SC against weeds in maize Report No.: 044GPSE202205 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/06 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the efficacy of Terbutylazyna 500 SC against weeds in maize Report No.: 044GPSE202206 Green & Property Consulting Anna Huszcza-Podgórska, GEP | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |

H-01-2022

Part A - National Assessment

Version April 2024

Applicant version

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| | | | Unpublished | | | | |
| KCP 6.2/07 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the efficacy of Terbutylazyna 500 SC against weeds in maize Report No.: 044GPSE202207 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/08 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the efficacy of Terbutylazyna 500 SC against weeds in maize Report No.: 044GPSE202208 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/09 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the selectivity of Terbutylazyna 500 SC in maize Report No.: 045GPSS202201 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/10 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the selectivity of Terbutylazyna 500 SC in maize Report No.: 045GPSS202202 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/11 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the selectivity of Terbutylazyna 500 SC in maize Report No.: 045GPSS202203 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 6.2/12 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the selectivity of Terbutylazyna 500 SC in maize Report No.: 045GPSS202204 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |

H-01-2022

Part A - National Assessment

Version April 2024

Applicant version

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
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| KCP 6.2/13 | Anna Huszcza-Podgórska | 2023 | Field study to evaluate the selectivity of Terbutylazyna 500 SC in maize Report No.: 045GPSS202205 Green & Property Consulting Anna Huszcza-Podgórska, GEP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 7.3/01 | Nabanita Sam | 2023 | <i>IN VITRO</i> PERCUTANEOUS DERMAL ABSORPTION STUDY OF TERBUTHYLAZINE, FORMULATED AS H-01-2022 THROUGH HUMAN SKIN STUDY No.: AG-G0929 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri Sp. z o.o. |
| KCP 9.2.4/01 | Tabor E | 2024 | H-01-2022 Calculation of predicted environmental concentrations of terbuthylazine and its metabolites in groundwater after application to maize using the FOCUS groundwater scenarios (FOCUS PEARL, FOCUS PELMO) Company Report No: EST/1/2024 ESTICON Sp. z o.o. GLP: No Published: No | N | N | Not relevant | ProAgri International Sp. z o.o. |
| KCP 9.2.5/01 | Tabor E | 2024 | H-01-2022 Calculation of Predicted Environmental Concentrations of terbuthylazine and its metabolites in surface water after application to maize using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/2/2024 ESTICON Sp. z o.o. GLP: No Published: No | N | N | Not relevant | ProAgri International Sp. z o.o. |
| KCP 10.2.1.2/01 | Rachana AR | 2023 | H-01-2022: <i>Daphnia magna</i> , Acute Immobilisation Test. Study Code: AG-G1146 Source: Eurofins Advinus Agrosciences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |

H-01-2022

Part A - National Assessment

Version April 2024

Applicant version

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
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| KCP 10.2.1.3/01 | Rachana AR | 2023 | H-01-2022: Alga, growth inhibition test with <i>Raphidocelis sub-capitata</i> . Study Code: AG-G1147 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.2.1.4/01 | Likith NG | 2023 | H-01-2022 <i>Lemma</i> , Growth Inhibition Test. Study Code: AG-G1148 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.2.1.4/02 | Likith NG | 2023 | H-01-2022 Water-sediment <i>Myriophyllum spicatum</i> toxicity Study Code: AG-G1158 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.3.1.1.1/01 | Gangadhar RS | 2023 | H-01-2022: Acute oral toxicity test in honey bees. Study code: AG-G1150 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.3.1.1.2/01 | Gangadhar RS | 2023 | H-01-2022: Acute contact toxicity test in honey bees. Study Code: AG-G1151 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.3.1.1.2/02 | Gangadhar RS | 2023 | H-01-2022: Chronic oral toxicity test in honey bee (<i>Apis mellifera</i> L.). Study Code: AG-G1152 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |

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|--------------------|--------------|------|--|-------------------------|--------------------------------|---|-------------------------------------|
| KCP 10.3.1.4/01 | Gangadhar RS | 2023 | H-01-2022: Honeybee (<i>Apis mellifera</i> L.) larval toxicity test, repeated exposure Study Code: AG-G1149 Source: Eurofins Advinus Agroservices India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.3.2.1/01 | Mautino G | 2023 | Effects of H-01-2022 (terbuthylazine 500 g/L) on parasitoid <i>Aphidius rhopalosiphii</i> in the laboratory – Standard laboratory test Study Code: 1013.H.SAG23/r Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.3.2.1/02 | Mautino G | 2023 | Effects of H-01-2022 (terbuthylazine 500 g/L) on predator mite <i>Typhlodromus pyri</i> in the laboratory – Standard laboratory test Study Code: 1014.H.SAG23/r Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.4.1.1/01 | Vishala N | 2023 | H-01-2022: Earthworm reproduction test (<i>Eisenia fetida</i>) Study Code: AG-G1153 Source: Eurofins Advinus Agroservices India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.4.2.1/01 | Mautino G | 2023 | Predatory mite <i>Hypoaspis (Geolaelaps) aculeifer</i> reproduction test in soil with H-01-2022 (terbuthylazine 500 g/L) Study Code: 1015.H.SAG23/r Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.4.2.1/02 | Gangadhar RS | 2023 | H-01-2022: <i>Folsomia candida</i> , collembolan reproduction test in soil Study Code: 1015.H.SAG23/r Source: Eurofins Advinus Agroservices India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |

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| KCP 10.5/01 | Kiran YC | 2023 | Soil Microorganisms: Nitrogen Transformation Test of H-01-2022. Study Code: AG-G1155 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.6.2/01 | Vishala N | 2023 | H-01-2022: Seedling emergence and seedling growth test with terrestrial plants Study Code: AG-G1156 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |
| KCP 10.6.2/02 | Vishala N | 2023 | H-01-2022: Vegetative Vigour Test Study Code: AG-G1157 Source: Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished | N | Y | New study never submitted before to PL | ProAgri International Sp. z o.o. |

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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The following tables are to be completed by MS

H-01-2022

Part A - National Assessment

Version April 2024

Applicant version

List of data submitted by the applicant and not relied on

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List of data relied on and not submitted by the applicant but necessary for evaluation

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