

# **FINAL** REGISTRATION REPORT

## **Part B**

### **Section 0**

Product Background, Regulatory Context and  
GAP information

Product code: T-75WG-OR2-C

Product name(s): TOSCANA TOP 750 WG

Chemical active substance(s):

Tribenuron methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

## **CORE ASSESSMENT**

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2020

MS Finalisation date: 15/10/2021

## Version history

When	What
December 2020	First submission for product authorization to zRMS.
02/2021	Dossier sent for evaluation to Merit Mark (PL)
08/2021	zRMS finalised evaluation
10/2021	Evaluation after commenting period - RR

---

## Table of Contents

<b>0</b>	<b>Product background, regulatory context and GAP information .....</b>	<b>4</b>
0.1	Introduction.....	4
0.1.1	Reason for application .....	4
0.1.2	Details of zRMS(s) and concerned MS .....	4
0.1.2.1	Tribenuron-methyl .....	4
0.1.3	Regulatory history of the product .....	5
0.2	zRMS conclusion .....	5
<b>Appendix 1</b>	<b>ALL intended uses .....</b>	<b>11</b>

Evaluator comments:

The text highlighted in grey was provided by the evaluator.

## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

#### 0.1.1 Reason for application

The dossier is submitted for the registration of a new product TOSCANA TOP 75 WG containing active substance tribenuron-methyl.

This application under Article 33 of regulation 1107/2009 submitted by the applicant in December 2020 is for first authorisation of the product TOSCANA TOP 75 WG follows the data requirements of:

- Regulation (EC) No. 283/2013 for the active substance tribenuron-methyl, and,
- Regulation (EC) No. 284/2013 for the plant protection product TOSCANA TOP 75 WG

The Applicant CIECH Sarzyna S.A. is the owner of most of studies conducted for TOSCANA TOP 75 WG (named during study phase: T-75WG-OR2-C or tribenuron metyl 75 WG). For some data for formulation CIECH Sarzyna S.A. has obtained Letter of Access from its owner Proplan Plant Protection Company, S.L.

For the active substance Tribenuron-methyl the applicant possesses letter from Proplan Plant Protection Company, S.L. in which access to all studies and statements presented in Data Matching renewal dossier for tribenuron-methyl, positively evaluated as equivalent by Sweden, was granted.

#### 0.1.2 Details of zRMS(s) and concerned MS

**Table 0.1-1: Overview of zRMS and cMS**

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	-	-
Central zone	PL – TOSCANA TOP 75 WG	-
Southern zone	-	-
Inter-zonal	-	-

##### 0.1.2.1 Tribenuron-methyl

**Table 0.1-2: Summary of regulatory history of CAS No: 101200-48-0**

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	<u>Current legislation:</u> Commision Directive 05/54/EC Reg. (EU) No. 2018/1913. Reg. (EU) No. 540/2011.  <u>Old legislation:</u> Reg. (EU) No 2017/1511 , Reg. (EU) No 2018/1262 , Reg. (EU) No 533/2013
RMS	SE

<b>Status</b>	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.02.2019
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	N/A
Date of final Commission (re-registration) deadline (Step 2)	N/A
Current expiration of approval	30.01.2034
Low risk substance or Candidate for Substitution?	No.

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

In this overall assessment Member States must pay particular attention to:

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tribenuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account.

In this overall assessment Member States must pay particular attention to the protection of non-target terrestrial plants, higher aquatic plants and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.

Conclusion on the peer review of the pesticide risk assessment of the active substance tribenuron methyl (EFSA Journal 2017;15(7):4912), provide the relevant information on the evaluation or a reference to where such information can be found.

**Table 0.1-3: Information on minimum purity of Tribenuron-methyl**

<b>EU agreed minimum purity from Inclusion Directive or Implementing regulation</b>	<b>(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **</b>
minimum purity of active substance: 960 g/kg	minimum purity of active substance: 975 g/kg. Equivalence report available: Y RMS: ES

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\*. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

### 0.1.3 Regulatory history of the product

Not relevant, first authorisation.

## 0.2 zRMS conclusion

### Section 1, 2 and 4. Identity, physical and chemical properties and further information

Two-year shelf life is accepted

Based on physicochemical properties the PPP is not classified.

### Section 3. Efficacy

T-75WG-OR2-C/TOSCANA TOP 75 WG is intended to control a wide range of dicotyledonous weeds in winter and spring cereals. 120 tests conducted in 2016-2017, on 40 weed species in 3 climate EPPO zones confirmed the high effectiveness of this herbicide. The minimum effective dose was set at 20 g/ha for autumn application and 25g/ha for spring application in winter cereals. In spring cereals, the minimum dose for effective weed control was 20 g/ha. The herbicide is intended for a single application during the growing season. Toscana Top 75 WG it is effective in controlling a wide range of weed species. The data obtained in the experiments confirm the proposed uses.

The effectiveness of the studied herbicide obtained in the experiments confirms the correctness of the information in the label. It is appropriate to divide the weeds into susceptible or moderately susceptible weeds for autumn or spring application for winter cereals or spring application for spring cereals. Tribenuron methyl is very effective in controlling a very wide range of weeds in cereal crops.

In Poland, resistant biotypes of chamomile (*Matricaria chamomilla*), field poppy (*Papaver rhoeas* L.), cornflower (*Centaurea cyanus*) mayweed (*Tripleurospermum inodorum*) were identified. Cases of tribenuron methyl resistance is indicated in the HRAC database. The applicant has presented in the label important elements of the anti-immune policy.

Toskana Top 75 WG shows high selectivity towards cereals. No adverse plant symptoms or negative effects of the herbicide on cereal yield were observed. The data obtained in the experiments confirm these features.

The results obtained in the experiments justify the needed for registration of the studied agent for weed control in cereals in Poland.

The data provided in dRR confirm the above applications and authorize the registration of Toscana Top 75 WG in Poland.

The application is submitted for registration of plant protection product TOSCANA TOP 75 WG in Poland according to art. 33 of Regulation 1107/2009. The zRMS is Poland.

The dRR is drafted correctly and contains appropriate and sufficient data on the performance of the herbicide tested. These data provide the basis for registration of the studied agent in Poland.

Plant protection product T-75WG-OR2-C/TOSCANA TOP 75 WG/Tribenuron-methyl/ shows high efficiency in controlling a large number of weeds in the cultivation of winter and spring cereals. Its activity also covers particularly weighty species. It is highly selective relative to cereals. In Poland 4 resistant biotypes were identified. The benefits of tribenuron-methyl justify a policy on the use of herbicides based on this a.s. The wide spectrum of activity of this herbicide and its high effectiveness, as well as the possibility of application in the spring or autumn season indicate the significant usefulness for agricultural practice and thus justify expediency of registration in Poland.

#### Section 5. Analytical Methods

The analytical method used for analysing the active substance in the PPP is accepted.

Data gap:

ILV method for tribenuron-methyl analysis in products of animal origin is required.

#### Section 6. Mammalian Toxicology

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

Skin Sens.1, H317; STOT RE 2, H373

Exposure data:

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

#### Section 7. Metabolism and Residues

Critical GAP for TOSCANA TOP 75 WG on cereals (wheat, triticale, barley, rye): 1 appl., max. BBCH-39, max application rate: 18.75 g a.s/ha, PHI- not applicable

EU GAP on wheat, barley, oats and rye (SANTE/11859/2017 Rev 4, 24 October 2018): 1 appl., max application rate 24 g a.s./ha on winter cereals and 22.5 g a.s./ha on spring cereals in max BBCH-39; PHI-not applicable when harvest at maturity. 28 for harvest as forage/ silage before maturity.

EU GAP covers the uses proposed on cereals for TOSCANA TOP 75 WG.

Critical GAP for TOSCANA TOP 75 WG on *Miscanthus* sp. (MISSS): 1 appl., max. BBCH-14, max application rate: 18.75 g a.s/ha, PHI- not applicable

Critical GAP for TOSCANA TOP 75 WG on grasses grown for seeds: 1 appl., max. BBCH-39, max application rate: 18.75 g a.s/ha, PHI- not applicable

EU GAP on grass for feed or seed (SANTE/11859/2017 Rev 4, 24 October 2018): 1 appl., max. BBCH-13, max application rate: 7.5 g a.s/ha, PHI- not applicable

Miscanthus sp., and grasses grown for seeds are not used as food or feed therefore residue studies are not required.

#### Stability

The storage stability study were evaluated at EU level. According to the EFSA Journal 2017;15(7):4912:

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)
High water content	Wheat forage	~ -18°C	24 months
High oil content			
	Cotton seed	~ -20°C	14 months
	Sunflower seed	~ -20°C	12 months
High protein content	Dried been	~ -20°C	18 months
High starch content	Wheat grain	~ -20°C	37 months
High acid content	Orange	~ -20°C	18 months
Others			
	Cotton gin trash	~ -20°C	18 months
	Wheat hay	~ -20°C	18 months
	Wheat straw	~ -20°C	37 months

The residue definition including metabolites is still provisional and therefore unprotected stability studies are adequate to support the intended uses proposed in the GAP table for TOSCANA TOP 75 WG. The new residues studies submitted by the Applicant includes tribenuron methyl residue and were performed in less than 30 days. Additional studies are not required.

#### Plant metabolism

Based on the available data EFSA concluded that *the residue definition for monitoring is proposed by default as tribenuron-methyl. For risk assessment, besides tribenuron-methyl, it is proposed to include IN-D5803, IN-G7462, IN-B5685 (sulfonamide-related compounds) and IN-L5296, IN-37739 (free and conjugated), IN-R9805, IN-A4098 (triazine amine related compounds) in the residue definition. This proposal will be reconsidered pending upon the toxicity of these compounds and their magnitude in all relevant crops.*

The Applicant submitted additional study on metabolism in wheat however according to this study the metabolism was less extensive, with tribenuron-methyl as the major compound at PHI 16 d (around 60% of TRR). Additionally, only three major metabolites were identified (IN-L5296, IN-D5803 and IN-R9805) and a different metabolic pathway than evaluated at EU level was proposed. Nevertheless, this study was proposed as equivalent to protected metabolism studies and was accepted in data matching (RMS Sweden, October 2019).

#### Confined rotational crop study

*No tribenuron-methyl was detected, and residues of its degradation products were negligible in any of the crop parts relevant for human consumption. It should be noted however that the relevant metabolite IN-A4908 found in beet foliage (up to 0.019 mg/kg, 30 PBI). The genotoxic potential of IN-A4908 cannot be ruled out. Identified metabolites show a similar metabolic pathway compared with primary metabolism and rotational studies and no specific residue definition has to be derived (EFSA Journal 2017;15(7):4912).*

The genotoxic potential of the metabolite IN-A4098 was evaluated in the Scientific Opinion from the PPR Panel (EFSA Journal 2020;18(3):6053) tends to exclude the potential of triazine-amine to induce gene mutations and clastogenicity but not aneugenicity: *Based on the overall weight of evidence, the cross-cutting WG genotoxicity concluded that there is no concern for the potential of triazine amine to induce gene mutations and clastogenicity. The crosscutting WG genotoxicity noted that the potential to induce numerical chromosomal aberrations (aneugenicity) was not adequately investigated. For a con-*

*clusion, an in vitro micronucleus assay performed with triazine amine would be needed. The PPR Panel agreed with the assessment of the cross-cutting WG genotoxicity.*

#### Residues in plants

The Applicant submitted additional studies (n=7, field trials in Poland (n=2), Hungary (n=2), Germany (n=2) and UK) of magnitude the tribenuron methyl residues in wheat. The doses used in the studies were in line with that proposed in GAP (difference does not exceed 25%). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39). Both trials carried out in Poland and both in Hungary came from the same place in each country (distance less than 20 km) and therefore cannot be considered independent. This means that 5 trials can be considered independent. Nevertheless, taking into account that all studies indicate the absence of tribenuron methyl residues in wheat grain and straw above the detection limit (0.003 mg/kg), it should be considered that the number of field trials for tribenuron methyl is sufficient. Information on the analytical parts of the studies is described in Part B5 and has been fully accepted.

According to SANTE/2019/12752, it is possible to extrapolate the results of the residue studies in wheat to barley and rye if the treatment takes place before forming of the edible part. This condition is met, the max BBCH proposed in the GAP for TOSCANA TOP 75 WG is 39.

The Applicant did not provide residue studies of tribenuron methyl metabolites included in the provisional residue definition. Given that no data on their toxicity are available and that the genotoxicity of some metabolites cannot be ruled out, the lack of residue studies showing their absence in the plant after harvest indicates that a complete consumer risk assessment cannot be carried out. However, it should be noted that the genotoxic potential of the metabolite IN-A4098 was evaluated in the Scientific Opinion from the PPR Panel (EFSA Journal 2020;18(3):6053) tends to exclude the potential of triazine-amine to induce gene mutations and clastogenicity but not aneugenicity.

Given that definition which contains metabolites is temporary, and renewal of approval includes, among others, lack of data in this field, the results of field trials presented by the Applicant, relation only to tribenuron-methyl (definition 1) was provisionally considered sufficient. **The Applicant shall provide results of field trials for metabolites included in the provisional residue definition for risk assessment no later than two years after authorization TOSCANA TOP 75 WG for use. In addition, due to the data gaps identified during the peer review this assessment is considered tentative and should be reassessed when evaluation of missing data becomes available at Community level.**

#### Residues in succeeding crops

According to the EFSA Journal 2017;15(7):4912: *Tribenuron-methyl 50SG (L5300 305) was applied to bare soil at a rate of 30 g tribenuron-methyl/ha at 2 test sites. Since for one study only limited investigation was conducted, (tribenuron-methyl, IN-L5296, IN-R9805, IN-D5803 or INB5528), while IN-A4908 found in the metabolism study up to (0.019 mg/kg, 30 PBI) was not analysed for, the field rotational crop studies are considered insufficient (data gap).*

#### Residues in livestock

No new data submitted in the framework of this application. According to the EFSA Journal 2017;15(7):4912: *Tribenuron-methyl metabolism in livestock was investigated in laying hens and lactating goats with both triazine- and phenyl-labelled tribenuron methyl. In goat, the major compound was IN-A4098, accounting from 35% up to 81% TRRs in all animal matrices. IN-QKK48 (hydroxyl tribenuron-methyl) was recovered in whole milk (0.6–10% TRR), kidney (14.5–18% TRR) and fat (12% TRR) for both labellings as well as saccharin that occurred in significant levels in all matrices (13–71% TRR). For poultry, IN-A4098 was also recovered at significant levels from 40% up to 62% of TRR in all commodities, in addition IN-L5296 accounted up to 17% of TRRs. Based on these studies, the agreed animal residue definition for monitoring is tribenuron-methyl for all matrices while for risk assessment separate residue definitions are proposed as following:*

*1) Ruminant matrices: tribenuron methyl and IN-A4098*

*2) Poultry matrices: tribenuron-methyl, IN-L5296, IN-A4098, and IN-D5803.*



*The way the risk assessment residue definitions will be expressed is pending upon the requested toxicological profile of these compounds (see data gap in Section 2).*

*The potential inclusion of IN-QKK48 and saccharin in the risk assessment residue definition for ruminants was also discussed during the expert's meeting and the majority opinion was not to include these compounds in the residue definition considering the highly overdosed metabolism studies and the lower toxicity of saccharin compared to the parent compound (ADI: 3.8 mg/kg bw per day; Section 2). The finalisation of the livestock exposure assessment is however pending the assessment of the relevant residue in food and feed commodities. Therefore, pending upon the outcome of the outstanding data on the magnitude of the pertinent compounds identified in primary and rotational crops and their toxicity, the livestock dietary burden calculation should be reconsidered (data gap). Whether the compounds provisionally included in the risk assessment residue definition for plant, significantly contribute to the livestock dietary burden, their potential transfer in animal matrices may need to be further investigated.*

*NOTE: Livestock dietary burden cannot be finalised for the time being. Pending upon the outcome of the outstanding data on the magnitude of the pertinent compounds identified in primary and rotational crops and their toxicity, the livestock dietary burden calculation should be reconsidered.*

Taking into account the above, dietary burden calculations presented by the Applicant for tribenuron methyl should be considered sufficient for the purposes of this assessment. However, as new data assessed at Community level become available, this dossier should be completed and reassessed.

#### Risk assessment

The risk assessment was conducted for residues of tribenuron-methyl only. The consumer risk assessment (chronic and acute) was calculated using EFSA PRIMo rev. 3.1 for all MRLs in force (Reg. (EU) 2015/1040). Results indicated the highest estimate of chronic dietary intake is 12% of the ADI (NL toddler). The results of the acute dietary assessment (IESTI) do not identify any exceedances of the ARfD (max 0,8% ARfD).

The chronic and the short term intakes of tribenuron methyl residues are unlikely to present a public health concern.

Taking into account the provisional residue definition for risk assessment, and further clarification with regard to the genotoxic potential of metabolites IN-A4098, IN-L5296 and IN-B5685 the consumer risk assessment is not finalised for the representative uses – data gap identified at Community level.

#### Conclusion

**Authorization can be granted. No specific mitigation measures should apply.**

**The Applicant shall provide ILV method for tribenuron methyl analysis in products of animal origin and results of field trials for metabolites included in the provisional residue definition for risk assessment no later than two years after authorization TOSCANA TOP 75 WG for use.**

**In addition, due to the data gaps identified during the peer review this assessment is considered tentative and should be reassessed when evaluation of missing data becomes available at Community level.**

#### Section 8. Environmental Fate

In accordance with proposed pattern use, an exposure assessment for the formulation TOSCANA TOP 75 WG was submitted and sufficient.

#### Section 9. Ecotoxicology

In accordance with proposed pattern use, risk assessment to non-target organisms for the formulation of TOSCANA TOP 75 WG was sufficient.

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of TOSCANA TOP 75 WG as herbicide in cereals at the maximum application rate of 25 g product/ha (uses 1-13) and to grasses at the application rate of 20 g product/ha (uses 14,15) achieved acceptable risk to non-target organisms.

#### Section 10. Assessment of the relevance of metabolites in groundwater

The submitted PEC<sub>gw</sub> values for metabolites of active substance are in accordance with PELMO and

PEARL PEC<sub>gw</sub> assessment.

All PEC<sub>gw</sub> values are above the trigger value of 0.1 µg/L and represents the worst case (winter cereals, autumn application every year) with exception for metabolite IN-00581 (winter cereals, autumn application every third year).

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

All but 14-15 at the maximum safe application rate 20 g product/ha

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

**Ecotoxicology:** Uses 14-15 at the application rate 25 g product/ha are considered non-safe for mammals on the basis of EU methodology.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

**Fate & behaviour:** For alkaline soils the autumn application in winter cereals is acceptable if the formulation is used every third year.

**Ecotoxicology:** Effects on terrestrial vertebrates other than birds – higher tier risk assessment need to be confirmed. Precautions to reduce the environmental concentrations resulting from TOSCANA TOP 75 WG

applications are required for:

- aquatic organisms
- non-target terrestrial plants

All uses/ GAPs are covered by established MRLs.

## Appendix 1 ALL intended uses

PPP (product name/code): T-75WG-OR2-C/TOSCANA TOP 75 WG  
Active substance 1: Tribenuron-methyl  
Active substance 2: N/A  
Safener: N/A  
Synergist: N/A  
Applicant: CIECH Sarzyna S.A.  
Zone(s): central <sup>(d)</sup>  
Verified by MS: ~~no~~yes

GAP , date: December 2020  
Formulation type: WG <sup>(a, b)</sup>  
Conc. of as 1: 750 <sup>(c)</sup>  
Conc. of as 2: N/A  
Conc. of safener: N/A <sup>(c)</sup>  
Conc. of synergist: N/A <sup>(c)</sup>  
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. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha ( <sup>(i)</sup> )
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Winter soft wheat (TRZAW), Winter rye (SECCW), Winter triticale (TTLWI), Winter barley (HORVW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Autumn BBCH 13 – 29	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	-
2	PL	Winter soft wheat (TRZAW), Winter rye	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	-

		(SECCW), Winter triticale (TTLWI), Winter barley (HORVW)											
3	PL	Spring soft wheat (TRZAS), Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	-
4	DE	Winter soft wheat (TRZAW), Winter rye (SECCW), Winter triticale (TTLWI), Winter barley (HORVW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Autumn BBCH 13 – 29	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure
5	DE	Winter soft wheat (TRZAW) Winter rye (SECCW), Winter triticale (TTLWI) Winter barley (HORVW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure
6	DE	Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure
7	HU	Winter soft wheat (TRZAW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure
8	HU	Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure
9	RO	Winter soft wheat (TRZAW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure

10	RO	Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure
<b>Minor uses according to Article 51 (zonal uses)</b>													
11	PL	Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Annual dicotyledonous weeds	Broadcast - foliar	Autumn BBCH 13 – 29	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	There are no phytotoxicity studies for minor uses. It is possible to register in Poland without an effectiveness test pursuant to Art 51 of the Regulation 1107/2009
12	PL	Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	There are no phytotoxicity studies for minor uses. It is possible to register in Poland without an effectiveness test pursuant to Art 51 of the Regulation 1107/2009
13	PL	Spring rye (SECCS), Spring triticale (TTLWS), Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	In Poland spring triticale is not included in the list of minor uses. There are no phytotoxicity studies for minor uses. It is possible to register in Poland without an effectiveness test pursuant to Art 51 of the Regulation 1107/2009
14	PL	Miscanthus sp. (MISSS)	F	Annual dicotyledonous weeds	Broadcast - foliar	BBCH 12 -14	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 15.00 ±8,75 g as/ha b) 15.00 ±8,75 g as/ha	200 / 400	n.a.	There are no phytotoxicity studies. It is possible to register in Poland without an effectiveness test pursuant to Art. 51 of the Regulation 1107/2009 *

15	PL	Grasses grown for seeds	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 <del>5</del> kg/ha; b) 0,02 <del>5</del> kg/ha	a) 15.00 <del>±8,75</del> g as/ha b) 15.00 <del>±8,75</del> g as/ha	200 / 400	n.a.	as above *
<b>Minor uses according to Article 51 (interzonal uses)</b>													

<b>Remarks table heading:</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

**Fate & behaviour:** For alkaline soils the autumn application in winter cereals is acceptable if the formulation is used every third year.

**Ecotoxicology:** Uses 14, 15: To achieved acceptable risk assessment for mammals in Section B9 reduction of application dose to maximum safe application dose of 20 g product/ha was needed\*