

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: T-75WG-OR2-C

Product name(s): TOSCANA TOP 75 WG

Chemical active substance:

Tribenuron methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland
(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2020

MS Finalisation date: 15/10/2021

Version history

When	What
12/2020	First submission for product authorisation to zRMS.
02/2021	Dossier sent for evaluation to Merit Mark (PL)
06/2021	Correction of the first submission on product.
08/2021	zRMS finalised evaluation
10/2021	Evaluation after commenting period - RR

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PART A

RISK MANAGEMENT

1 Details of the application

This application was submitted by company CIECH Sarzyna Spółka Akcyjna, ul Chemików 1, 37-310 Nowa Sarzyna, Poland in December 2020.

The information, data and assessments provided in Registration Report, Parts B includes assessment of data and information relating to TOSCANA TOP 75 WG where that data has not been considered in the EU review. Otherwise assessments for the safe use of TOSCANA TOP 75 WG have been made using endpoints agreed in the EU review of tribenuron-methyl.

1.1 Application background

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 uses applied for spring and winter cereals (autumn and spring application). The application is also submitted for extension of uses of the product TOSCANA TOP 75 WG on minor uses i.e.: durum wheat, spelt wheat, einkorn wheat, emmer wheat (autumn application); durum wheat, spelt wheat, einkorn wheat, emmer wheat (spring application); spring rye, spring triticale, durum wheat, spelt wheat, einkorn wheat, emmer wheat (spring application); miscanthus sp. and grasses grown for seeds (spring application).

1.2 Letters of Access

Applicant possess Letter of Access from the Task Force “Tribenuron TF”/ Proplan to alternative data package for active substance Tribenuron-methyl to data package for the product Toscana/Toscana 75 WG from Proplan Plant Protection Company.

For formulation TOSCANA TOP 75 WG Applicant has also conducted and submitted own studies on which are sufficient to evaluate of the product.

1.3 Justification for submission of tests and studies

All tests and studies for TOSCANA TOP 75 WG are submitted to meet the requirements of Regulation (EC) No. 284/2013. These studies are necessary to gain the authorisation.

Please notice that the product name TOSCANA TOP 75 WG, T-75WG-OR2-C and PP-108H is the same commercial formulation containing 750 g/kg tribenuron methyl.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4

2 Details of the authorization decision

2.1 Product identity

Product code	T-75WG-OR2-C
Product name in MS	TOSCANA TOP 75 WG
Authorization number	N/A
Function	herbicide
Applicant	CIECH Sarzyna S.A.
Active substance(s) (incl. content)	Tribenuron-methyl 750 g/kg

Formulation type	WG – water dispersible granule
Packaging	<p>TOSCANA TOP 75 WG will be commercially available in the following packages:</p> <ul style="list-style-type: none"> – 10g, 20 g, 50, 100 g, 250 g – sachets/bags made from: <ul style="list-style-type: none"> •PE contained in a cardboard boxes •METLAM (polyester/aluminium/polyethylene) •METLAM (polyester/aluminium/polyethylene) contained in a cardboard boxes - 10g, 20 g, 50, 100 g - Water soluble bags in a METLAM – 150 ml, 300 ml, 600 ml – bottles made from HDPE
Coformulants of concern for national authorizations	not applicable
Restrictions related to identity	n/a
Mandatory tank mixtures	n/a
Recommended tank mixtures	n/a

2.2 Conclusion

Efficacy: 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 it in the spring or autumn season indicate the significant usefulness for agricultural practice and thus justify expediency of registration in Poland.

Residue section: 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.

Fate & Behaviour: The evaluation of the application for T-75WG-OR2-C / TOSCANA TOP 75 WG resulted in the decision to grant the authorization in: uses 1-8. For alkaline soils the autumn application in winter cereals is acceptable if the formulation is used every third year.

Ecotoxicology: The evaluation of the application for T-75WG-OR2-C / TOSCANA TOP 75 WG resulted in the decision to grant the authorization in: cereals (uses 1-6).

For TOSCANA TOP 75 WG uses in grasses grown for seeds (use 8) and miscanthus (use 7) rate of 20 g product/ha is considered safe for terrestrial vertebrates other than birds. For these uses the authorisation can be granted for maximum safe application rate of 20 g product/ha.

2.3 Substances of concern for national monitoring

National monitoring data is not available/known to the applicant.

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:	Skin Sens. 1, H317 STOT RE 2 Aquatic Acute 1
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	Aquatic Chronic 1
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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:	GHS08, GHS09, GHS07
Signal word:	Warning
Hazard statement(s):	H373 - May cause damage to organs through prolonged or repeated exposure. H317 - May cause an allergic skin reaction H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P260 Do not breathe spray. P314 Get medical advice/attention if you feel unwell. P280 Wear protective gloves/protective clothing P302+P352 IF ON SKIN: Wash with plenty of water P391 Collect spillage. P501 Dispose of contents/container to authorised entity
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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).
SPe2	To protect groundwater do not apply to alkaline soils more often than every third year, if formulation is applied to winter cereals in autumn application.
SPe3	To protect non-target plants respect <u>Winter cereals and minor uses at the application rate 25 g product/ha</u> - unsprayed buffer zone of 1 m with of 75% drift reducing technology or, - unsprayed buffer zone of 5 m with no drift reducing technology to non-agricultural land <u>Spring and winter cereals and minor uses at the application rate 20 g product/ha</u> - unsprayed buffer zone of 1 m and use of 50% drift reducing technology or, -unsprayed buffer zone of 5 m buffer zone with no drift reducing technology to non-agricultural land

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

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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:	
-	-
Worker protection:	
-	-
Integrated pest management (IPM)/sustainable use:	
Mode of action (HRAC-group):	Tribenuron-methyl: B
Environmental protection	
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).
SPe2	To protect groundwater do not apply to alkaline soils more often than every third year, if formulation is applied to winter cereals in autumn application.
SPe3	To protect non-target plants respect <u>Winter cereals and minor uses at the application rate 25 g product/ha</u> - unsprayed buffer zone of 1 m with of 75% drift reducing technology or, - unsprayed buffer zone of 5 m with no drift reducing technology to non-agricultural land <u>Spring and winter cereals and minor uses at the application rate 20 g product/ha</u> - unsprayed buffer zone of 1 m and use of 50% drift reducing technology or, - unsprayed buffer zone of 5 m buffer zone with no drift reducing technology to non-agricultural land
Other specific restrictions	
respective code if available	no other requirements

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.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

GAP rev.1 date: December 2020

PPP (product name/code): TOSCANA TOP 75 WG/ T-75WG-OR2-C
Active substance 1: Tribenuron-methyl
Active substance 2: N/A
Safener: N/A
Synergist: N/A
Applicant: CIECH Sarzyna S.A.
Zone(s): central ^(d)
Verified by MS: yes
Field of use: herbicide

Formulation type: WG ^(a, b)
Conc. of as 1: 750 g/kg ^(c)
Conc. of as 2: N/A
Conc. of safener: N/A
Conc. of synergist: N/A
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	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 (SECCW), Winter triticale (TTLWI),	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.	-

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, 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 ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		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.	-
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
Minor uses according to Article 51 (zonal uses)													
4	PL	Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Annual dicotyledonous weeds	Broadcast - foliar	Autumn BBCH 13 – 23	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 phytotox- icity studies for minor uses. It is possible to register in Poland without an effectiveness test pursuant to Art 51 of the Regulation 1107/2009
5	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 phytotox- icity studies for minor uses. It is possible to register in Poland without an effectiveness test pursuant to Art 51 of the Regulation 1107/2009
6	PL	Spring rye (SECCS), Spring triticale (TTLWS), Durum wheat (TRZDU),	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 tritica- le is not included in the list of minor uses. There are no phytotox- icity studies for minor

[illegible]

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	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*

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 of cylindrical bright beige granules with light characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has no a self-ignition temperature until 400°C. In aqueous solution, it has a pH value around 6.01 at 20°C. There is no effect of high temperature on the stability of the formulation, since after 12 weeks at 35°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PE bags, HDPE bottles and water-soluble bags. Its technical characteristics are acceptable for a water dispersible granules (WG) formulation.

The intended concentration of use is 0.005% to 0.0125%.

3.2 Efficacy (Part B, Section 3)

TOSCANA TOP 75 WG is a water dispersible granules (WG) containing 750 g/kg of Tribenuron methyl and is intended to register in Poland as a herbicide for use in winter cereals (wheat, rye, triticale and barley) and spring cereals (wheat and barley) against annual dicotyledonous weeds, at target application rate 1,0 kg/ha.

Product may be applied post emergence in autumn (BBCH 13-29) or in spring (BBCH 13-39) with recommended water volume 100-400 L/ha and maximum one application per crop/season.

The registration is also connected with extension of uses of product TOSCANA TOP 75 WG on minor uses. The proposed scope of minor uses are.: durum wheat, spelt wheat, einkorn wheat, emmer wheat (autumn application); durum wheat, spelt wheat, einkorn wheat, emmer wheat (spring application); spring rye, spring triticale, durum wheat, spelt wheat, einkorn wheat, emmer wheat (spring application); miscanthus sp. and grasses grown for seeds (spring application).

3.3 Efficacy data

A total of 120 trials investigating the minimum effective dose and the effectiveness of TOSCANA TOP 75 WG against weeds were implemented in 2016 and 2017. Those trials were undertaken in winter wheat, winter barley, winter rye, winter triticale, spring wheat and spring barley.

Trials were located in the Maritime EPPO zone (Germany and United Kingdom, 54 trials) in, North-Eastern EPPO zone (Poland, 55 trials) and in the South-Eastern EPPO zone (Hungary and Romania, 11 trials). All trials were carried out by officially recognized organisations, in accordance with the Principles of Good Experimental Practices (GEP).

It has been demonstrated that the minimum effective dose of TOSCANA TOP 75 WG applied post-emergence for the control of dicotyledonous weeds is in winter cereals 20,0 g/ha in autumn and 25,0 g/ha in spring and also in spring cereals 20,0 g/ha, when compared with lower tested rates (15,0 g/ha or 12,0 g/ha) for which efficacy obtained was lower and less consistent. Therefore the target doses provided the optimum overall control and should be considered as effective against targeted weed species, for which activity of TOSCANA TOP 75 WG is claimed.

The efficacy of TOSCANA TOP 75 WG was investigated over 40 different weed species in all EPPO zones. Whatever the EPPO zone considered, application timing or crops, TOSCANA TOP 75 WG at target doses achieved a very high control (> 95% efficacy) or a high control (85-94.9% efficacy) against majority of weeds e.g. *Brassica napus*, *Capsella bursa-pastoris*, *Cyanus segetum*, *Lamium purpureum*, *Papaver rhoeas*, *Tripleurospermum inodorum* (winter application in winter cereal and spring application in spring cereal), *Stellaria media*.

Consequently, it is justified to claim the registration of one application of TOSCANA TOP 75 WG in autumn (BBCH 13-29) in winter cereals at 20 g/ha and in spring (BBCH 13-39) at dose 25,0 g/ha in winter cereals and 20 g/ha in spring cereals for the control of broad spectrum of annual dicotyledonous weeds.

3.3.1 Information on the occurrence or possible occurrence of the

development of resistance

Tribenuron-methyl belongs to the Sulfonylurea (HRAC group: B) chemical family of herbicides. Tribenuron-methyl inhibits the plant amino acid synthesis by blocking the normal function of the acetohydroxyacid synthase (AHAS) also known as acetolactate synthase (ALS) (weedsience.org). ALS is a key enzyme of the branched-chain amino acids isoleucine, leucine and valine (LaRossa and Schloss, 1984) and without proteins, plants starve to death (Pue and Guddat, 2014). However, the actual sequence of phytotoxic processes is unclear (weedsience.org).

According to the latter, against Tribenuron-methyl first evidence of resistance has been appeared in 1987 in United States (Idaho). Resistance have been observed later in several countries in 43 cases of broad-leaved weed species worldwide (Weed science, 2018). The risk of resistance to Tribenuron-methyl in cereals among broad-leaved weeds depends on the cropping systems and could be high in wheat, winter wheat and spring barley. So far, in Europe, 14 weed species have evolved resistance to Tribenuron-methyl in cereals crops and among which 13 have developed a cross-resistance.

The weeds presenting the highest number of declared cases of resistance, in cereals crops, in European countries are: *Stellaria media*, *Kochia scoparia*, *Papaver*, *Sinapsis arvensis*, *Tripleurospermum perforatum* and *Capsella bursa-pastoris*.

Tribenuron-methyl shows high effectiveness in combating dicotyledonous weeds in the early stages of plant development and high selectivity in relation to cereals.

In Poland, resistant biotypes of chamomile (*Matricaria chamomilla*), Ref.2018, field poppy (*Papaver rhoeas* L.), cornflower (*Centaurea cyanus*) Ref. 2013, 2020, mayweed (*Tripleurospermum inodorum*) Ref. 2018 were identified.

4 weed species originating in Poland were indicated on the list: Cases of tribenuron methyl resistance indicated in the HRAC database.

The research indicate that resistant biotypes of the mentioned species come from specific locations where methyl tribenuron was often used to protect cereals were often found in crop rotation. This favoured the emergence of resistant biotypes of the afore mentioned weed species.

Considering that TOSCANA TOP 75 WG has a single mode of action, and that resistances exist to herbicides with the same mode of action than Tribenuron-methyl as well as cross-resistance, some guidelines should be followed in order to prevent from resistance appearing against this active substance.

3.3.2 Adverse effects on treated crops

A total of 111 selectivity trials investigating the adverse effects on treated crops (phytotoxicity, impact on yield and on quality parameters) of TOSCANA TOP 75 WG on treated plants were implemented in 2016 and 2017 in Maritime EPPO zone (Germany and United Kingdom, 55 trials), North-east EPPO zone (Poland, 41 trials) and South-east EPPO zone (Hungary and Romania, 15 trials). Furthermore, phytotoxicity of TOSCANA TOP 75 WG was assessed in 120 efficacy trials..

Irrespectively of the EPPO climatic zone, in the majority of trials no phytotoxic symptoms were seen following application of TOSCANA TOP 75 WG at 12,0 – 25,0 g/ha at efficacy trials and 20,0 – 50,0 g/ha in selectivity trials. Even when phytotoxic symptoms were recorded – these symptoms were transitory and disappeared in the subsequent observations. Moreover, no negative or negligible effects were observed on the yield and the quality parameters such as grain moisture content (%), Thousand Grain Weight (g) , protein content (%), Hectoliter weight (kg/hl), following treatment with TOSCANA TOP 75 WG, irrespectively of the application timing or EPPO zone.

3.3.3 Observations on other undesirable or unintended side-effects

As a result of the risk assessment prepared in accordance to the EPPO guideline PP 1/207 (2) “Effects on succeeding crops” it could be assumed TOSCANA TOP 75 WG does not pose non acceptable risk for succeeding crops.

Therefore, if it is necessary to liquidate a plantation treated with the product as a result of damage to plants by frosts, diseases or pests other plants can be grown.

As a result of the risk assessment prepared in accordance to the EPPO guideline PP 1/256 TOSCANA TOP 75 WG does not pose risk for on other plants including adjacent crops.

During the performance of trials referred to in this dossier, no observations were recorded on negative or positive effects of TOSCANA TOP 75 WG on beneficial or other non-target organisms.

3.4 Methods of analysis (Part B, Section 5)

The method were successfully evaluated and meet the EU criteria with respect to precision, accuracy and linearity and fulfils requirements of SANCO/3030/99 rev.4.

3.4.1 Analytical method for the formulation

The content of active substance in the examined sample was determined by high performance liquid chromatography HPLC with UV/Vis detector using reversed phase column.
External standard method was used.

Tribenuron-methyl does not contain any impurity of toxicological or ecotoxicological concern.

The analytical methods were fully validated and meet the EU criteria with respect the linearity, accuracy and precision according to the requirements given in EU Commission Directive 96/46/EC and the guidance document SANCO/3030/99 rev. 4.

3.4.2 Analytical methods for residues

Adequate analytical methods are available to monitor all compounds given in the respective residue definition of tribenuron-methyl in food of plant and animal origin, soil, water and air.

Data gap:

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

3.5 Mammalian toxicology (Part B, Section 6)

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended even if no PPE are applied.

3.5.1 Acute toxicity

The applicant did not perform acute toxicity studies because of protection of animals used for experimental and other scientific purposes. According to Regulation (EC) No 1107/2009 “The use of non-animal test methods and other risk assessment strategies should be promoted”. Animal testing for the purposes of registration procedure should be minimized and tests on vertebrates should be undertaken as a last resort. The same approach is strongly recommended by Regulation (EC) No 1272/2008 which advise reducing testing on vertebrate animals and the number of animals involved.

Only for eye irritation and skin sensitisation the applicant presented existing studies to reduce the classification resulting from the calculation method. Skin sensitization study of PP-108H (Tribenuron methyl 75% WG) in guinea pigs [Guinea pig maximization test] is not accepted. Formulation is classified based on the content of active substance (75% w/w) and the harmonized classification of tribenuron-methyl as Skin Sens. 1, H317. Acute eye irritation study of PP-108H (Tribenuron methyl 75% WG) in rabbits is accepted. This study prove that TOSCANA TOP 75WG is not irritant to eyes.

3.5.2 Operator exposure

Using EFSA GD Exposure Calculator at the 75th percentile, operator exposures were estimated for maximum application rates of TOSCANA TOP 75 WG to cereals and minor crops and against the AOEL agreed in the EU review for Tribenuron-methyl. Results show that the risk for the operator using TOSCANA TOP 75 WG with vehicle mounted sprayer is acceptable even when no PPE is applied.

3.5.3 Worker exposure

The results of the exposure estimations based on EUROPOEM II and EFSA calculator show that the use of TOSCANA TOP 75 WG according to the list of intended uses presented in GAP Table, causes no

health risk for the worker because the calculated exposure level to Tribenuron-methyl is below of the values of AOEL for this active substances (assuming no PPE is used).

3.5.4 Bystander and resident exposure

The incidental short-time exposure of bystander and resident (children and adult) to Tribenuron-methyl contained in the formulation TOSCANA TOP 75 WG causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.

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

The use of product TOSCANA TOP 75 WG does not lead to unacceptable risk for consumer when applied according to the recommendations.

3.6.1 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 conclusion, 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 not-

ed 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 assess-

ment (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 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.

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

The predicted environmental concentrations (PEC values) in soil, surface water, sediment and groundwater were calculated following the proposed use patterns.

The alkaline and acidic conditions for DT₅₀ and Kfoc values were considered in PEC_{gw} and PEC_{sw} assessment.

Details of the PEC calculations are provided in Part B, Section 8 of this dRR.

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

The PEC values of TOSCANA TOP 75 WG, tribenuron-methyl and its metabolites in soil have been assessed with the ESCAPE model (Version 2.0, 5 September 2017), the focus groundwater interception values taken from FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version: 2.2, May 2014)) and the DT₅₀ values established in the EU peer review for tribenuron-methyl (EFSA Journal 2017;15(7):4912).

Presented calculations are acceptable and suitable input parameters for exposure assessment.

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

According to „ EFSA Journal 2017;15(7):4912, Conclusion on the peer review of the pesticide risk assessment of the active substance “tribenuron-methyl”, metabolites, i.e. IN-L5296, IN-A4098, IN-00581, IN-R9805, M2, IN-R9803 and IN-GK521 were identified in soil degradation studies which may move into groundwater. The tiered approach based on lab and field data was considered and accepted.

Calculations of the predicted environmental concentrations of tribenuron-methyl and its metabolites in groundwater were calculated for single application to winter and spring cereals and for each application recommended for use in both crops.

Also, the minor uses (grass) were considered in PEC_{gw} calculation. The predicted environmental concentrations (PEC) of tribenuron-methyl and its metabolites in groundwater have been determined for application of TOSCANA TOP 75 WG for three FOCUS scenarios, i.e. Châteaudun, Hamburg and Kremsmünster which are the most appropriate to reflect the soil and climatic conditions occurring in Poland.

For the intended use of TOSCANA TOP 75 WG in winter cereals with application in autumn, the results of modelling with FOCUS PELMO (v 5.5.3) & PEARL (v 4.4.4) show that the active substance tribenuron-methyl and its metabolites (IN-L5296, IN-A4098, IN-00581, IN-R9805 and IN-GK 521) are exceed

the concentrations of $\geq 0.1 \mu\text{g/L}$ according to use max. application rate 15 g a.s./ ha, in every year. However, when one application every three years was accepted to winter cereals at autumn application in alkaline soils) the results showed that PEC_{gw} of tribenuron-methyl in all FOCUS scenarios was $< 0.1 \mu\text{g/L}$. The PEC_{gw} values for the metabolites IN-A4098, IN-00581 and IN-GK 521 were above trigger value of $0.1 \mu\text{g/L}$ but stayed below $0.75 \mu\text{g/L}$. All results from PELMO & PEARL software demonstrated that the one application every 3rd year use of tribenuron-methyl at the rate of 15 g a.s./ha would not result in any risk to groundwater contamination. The results are summarized in Section 8 of the dRR.

The simulation runs were conducted for an annual application rate of the substance tribenuron-methyl of 18.75 g a.s./ha and 15 g a.s./ha on winter & spring cereals. Results of modelling with FOCUS PELMO & PEARL in the intended uses in winter and spring cereals showed that the active substance for tribenuron-methyl were $< 0.1 \mu\text{g/L}$ for all scenarios with all models. In addition, PEC_{gw} for the metabolites M2 and IN-R9805 (only for crop spring cereals) were always $< 0.1 \mu\text{g/L}$.

The information concerning the environmental metabolites IN-L5296, IN-A4098, IN-00581 and IN-R9805 assessment of their potential relevance with respect to the current SANCO guidance (SANCO/221/2000 rev.10, 25/02/2003) is provided in this dRR, Section 10 (Assessment of the relevance of metabolites in groundwater).

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

In accordance with the applicable requirements calculation of the PEC_{sw} and PEC_{sed} values for the active substance and relevant metabolites, degradation and reaction products in surface waters were presented. The PEC_{sw} and PEC_{sed} were calculated for single application to winter and spring cereals and for each application recommended for use in both crops. Also, the minor uses (grass) were considered in PEC_{sw} calculation. The calculations were carried out taking into consideration of data for active substance and metabolites listed in the „EFSA Journal 2017;15(7):4912, Conclusion on the peer review of the pesticide risk assessment of the active substance Tribenuron-methyl”.

Winter and spring cereals. The initial, short-term and long-term (actual and average time-weighted) values of PEC_{sw} and PEC_{sed} were calculated for tribenuron methyl and appropriate metabolites using STEPS 1-2 in FOCUS v.3.2, FOCUS SWASH v.5.3, FOCUS PRZM v.4.3.1, FOCUS MACRO v.5.5.4, FOCUS TOXSWA v.5.5.3 and SWAN v.5.0.1. As the PEC_{sw} values of tribenuron methyl derived from Step 3 indicated a possible risk for aquatic organisms, a calculation of PEC_{sw} values based on higher tier modelling (Step 4) was necessary. Calculations of PEC_{sw} using Step 4 were performed taking into account different mitigation measures. Higher tier Step 3 and Step 4 of further metabolites were not required for the aquatic risk assessment. For missing R1 scenario in spring cereals the PEC_{sw} values from winter cereals at autumn application was used.

The PEC_{sw} and PEC_{sed} were calculated for metabolites such as IN-L5296, IN-A4098, IN-00581, IN-R9805, M2, IN-D5803, IN-D5119, IN-GN815 and IN-GK521 following the FOCUS SW scheme up to Step 2.

Grasses. The initial, short-term and long-term (actual and average time-weighted) values of PEC_{sw} and PEC_{sed} were calculated for tribenuron methyl and appropriate metabolites using STEPS 1-2 in FOCUS v.3.2, FOCUS SWASH v.5.3, FOCUS PRZM v.4.3.1, FOCUS MACRO v.5.5.4, FOCUS TOXSWA v.5.5.3 and SWAN v.5.0.1. As the PEC_{sw} values of tribenuron methyl derived from Step 3 indicated a possible risk for aquatic organisms no further modelling was performed. For missing R1 scenario in grasses, the PEC_{sw} values from winter cereals at spring application as a worse case was used.

The PEC_{sw} and PEC_{sed} were calculated for metabolites such as IN-L5296, IN-A4098, IN-00581, IN-R9805, M2, IN-D5803, IN-D5119, IN-GN815 and IN-GK521 following the FOCUS SW scheme up to Step 2.

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

Based on the endpoints assessed for tribenuron methyl (EFSA Journal 2017;15(7):4912) the active substance Tribenuron-methyl is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Tribenuron-methyl due to volatilization with subsequent deposition should not be considered.

According to data regarding atmospheric degradation and behaviour of Tribenuron-methyl, the risk of atmospheric pollution of active substance following the use of TOSCANA TOP 75 WG is low.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The risk to birds and mammals from the proposed uses of TOSCANA TOP 75 WG was assessed according to EFSA guidance (EFSA Journal 2009; 7(12):1438).

Effects on birds

The risk assessment performed for birds indicate acceptable acute and long-term risk to birds exposed to tribenuron methyl following application of TOSCANA TOP 75 WG according to intended GAP.

Effects on terrestrial vertebrates other than birds

The risk assessment performed for mammals indicate acceptable acute and long-term risk exposed to tribenuron methyl and the relevant plant metabolite following application of TOSCANA TOP 75 WG for intended use in cereals.

Acute risk assessment performed for mammals indicate acceptable acute risk exposed to tribenuron methyl and the relevant plant metabolite following application of TOSCANA TOP 75 WG for intended use in grassland.

Acceptable long-term risk was not achieved for active substance and plant metabolite since the trigger value of 5 was not met for vole for the proposed application rate at TIER 1. Therefore, higher refinement was performed.

PT refinement for vole presented by the Applicant was not agreed by zRMS. Unacceptable risk for the tribenuron methyl and acceptable risk for its plant metabolite was assumed based on the refined proportions of feed item in the diet (PD). Taking to consideration that at the higher tier unacceptable long-term risk was assumed for tribenuron methyl in use of grasses the authorisation can not be granted for grasses at the application rate 25 g product/ha (uses 14, 15).

Thus, zRMS used the maximum safe application rate 15.00 g a.s/ha. In conclusion, acceptable risk for the tribenuron methyl and acceptable risk for its plant metabolite was assumed based on the refined proportions of feed item in the diet (PD) with maximum safe application rate to 15g a.s/ha.

Taking to consideration that at the higher tier acceptable long-term risk was assumed for tribenuron methyl in use of grasses the authorisation can be granted for grasses taking to consideration reduction of application rate to 15 g a.s/ha (uses 14, 15).

As the active substance Tribenuron-methyl has a log Pow value of < 3 it was not necessary to consider the risk to birds and mammals from secondary poisoning.

No risk to birds or mammals via drinking water was identified, as the ratio of the effective application rate to relevant endpoints was < 50 (threshold relevant to the Koc of tribenuron-methyl).

Regarding effects on other terrestrial vertebrate wildlife (reptiles and amphibians) no data/information available.

3.8.2 Effects on aquatic species

The use in spring cereals is covered by risk assessment for winter cereals. Moreover, autumn application covers the risk assessment of spring application.

Based on PEC/RAC calculations, no unacceptable risk is indicated for aquatic organisms considering all

envisaged GAP uses for TOSCANA TOP 75 WG.

For the relevant PL scenarios D3, D4 and R1, no unacceptable risk is indicated following the TOSCANA TOP 75 WG application. Thus, no mitigation measures are required on the label.

3.8.3 Effects on bees

The evaluation of the risk for bees has been performed in line with SANCO/10329/2002 rev 2 final. Based on results obtained for TOSCANA TOP 75 WG in oral and contact studies on honeybees all calculated hazard quotients are considerably less than trigger values, indicating that the formulation poses a low risk to bees. Therefore, a low risk to bees is expected from the application of TOSCANA TOP 75 WG according to the proposed GAP and no mitigation measures are required.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): the Applicant provided the chronic test on bees and chronic test for larvae for formulated product.

It should be noted that The Applicant presented Larval Toxicity Test with single exposure while larval toxicity test with repeated exposure should be provided to cover not only acute but also chronic exposure to larva.

However, it should be taken to consideration that TOSCANA TOP 75 WG is a herbicide used in cereals and contain only one active substance. Tribenuron-methyl does not have insecticidal mode of action and substantial data did not show toxicity on honey bee and other non-target arthropods. Also, only one application during the season will be done so repeated exposure is not likely to occur in the environment. Thus, for PL larval Toxicity test with single exposure would be accepted for the risk assessment purposes.

3.8.4 Effects on other arthropod species other than bees

Based on results obtained for TOSCANA TOP 75 WG in laboratory studies on *T. pyri* and *A. rhopalosiphi* the corresponding 'in-field' and "off-field" hazard quotients are below the trigger value of 2 indicating an acceptable 'in-field' and "off-field" risk to non-target arthropods, following application of TOSCANA TOP 75 WG according to the proposed GAP.

3.8.5 Effects on soil organisms

Risk to earthworms arising from the application of TOSCANA TOP 75 WG according to the intended GAP uses can be excluded as the trigger values of 5 for long-term risk were exceeded by far.

Effects on other soil macro - organisms were not investigated since there are no risks associated with the use of TOSCANA TOP 75 WG to arthropods other than bees.

The risk to soil microorganisms is acceptable since effects on the nitrogen transformations are acceptable at concentration which is higher than the maximum relevant PEC soil for the maximum application rate of active substance Tribenuron methyl and its relevant metabolite.

3.8.6 Effects on non-target terrestrial plants

The risk for non-target plants in the off-crop area is indicated to be acceptable when applying:

Winter cereals and minor uses at the application rate 25 g product/ha

- unsprayed buffer zone of 1 m with 75% drift reducing technology or,
- unsprayed buffer zone of 5 m with no drift reducing technology to non-agricultural land

Spring and winter cereals and minor uses at the application rate 20 g product/ha

- unsprayed buffer zone of 1 m with 50% drift reducing technology or,
- unsprayed buffer zone of 5 m with no drift reducing technology to non-agricultural land

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Additional tests on other non-target species are not required.

3.9 Relevance of metabolites (Part B, Section 10)

The submitted PECgw values for metabolites of active substance are in accordance with PELMO and PEARL PECgw assessment.

All PECgw 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).

Appendix 1 Copy of the product label

Uwagi do etykiet:

Fizykochemia – brak uwag do etykiety.

Toksykologia – dodano zwrot wskazujący rodzaj zagrożenia H317, dodano pictogram GHS07, dodano zwroty wskazujące środki ostrożności: P280 oraz P302+P352.

Pozostałości – brak uwag do etykiety.

Los i zachowanie w środowisku – dodano zapis „W uprawie zbóż ozimych na glebach zasadowych w aplikacji jesiennej dopuszcza się stosowanie środka raz na trzy lata.”

Ekotoksykologia –wprowadzono strefy ochronne, w przypadku upraw: miskant i trawy – produkcja nasiennej zmniejszono maksymalną/zalecaną dawkę dla jednorazowego zastosowania z 25 do 20 g/ha.

Skuteczność działania – zmieniono treść etykiety w zakresie „Działanie na chwasty” oraz „Stosowanie środka”.

Załącznik do zezwolenia MRiRW nr R - z dnia

Posiadacz zezwolenia:

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TOSCANA TOP 75 WG

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Tribenuron metylowy (związek z grupy pochodnych sulfonilomocznika) - **750 g/kg (75 %)**

Zezwolenie MRiRW nr R - z dnia

	
UWAGA	
H373 H317 H410	Może powodować uszkodzenie narządów poprzez długotrwałe lub narażenie powtarzane Może powodować reakcję alergiczną skóry. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P260 P314 P280 P302 + P352 P391 P501	Nie wdychać pyłu / rozpylonej cieczy. W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza. Stosować rękawice ochronne/odzież ochronną W PRZYPADKU DOSTANIA SIĘ NA SKÓRĘ: Umyć dużą ilością wody. Zebrać wyciek. Zawartość/pojemnik usuwać do podmiotu uprawnionego do utylizacji

OPIS DZIAŁANIA

TOSCANA TOP 75 WG jest herbicydem selektywnym o działaniu układowym, w formie granulatu do sporządzania zawiesiny wodnej (WG), stosowanym nalistnie, przeznaczonym do powszodowego zwalczania rocznych chwastów dwuliściennych w zbożach jarych i ozimych oraz w uprawach małoobszarowych takich jak: pszenica twarda ozima, pszenica orkisz ozima, pszenica płaskurka ozima, pszenica samopsza ozima, żyto jare, pszenżyto jare, pszenica twarda jara, pszenica orkisz jara, pszenica płaskurka jara, pszenica samopsza jara, miscant, trawy-produkcja nasienna.

Zgodnie z klasyfikacją HRAC substancja czynna tribenuron metylowy zaliczana jest do grupy B.

DZIAŁANIE NA CHWASTY

Środek pobierany jest głównie przez liście chwastów, w mniejszym stopniu przez korzenie. W roślinach wrażliwych hamuje podział komórek w stożkach wzrostu zatrzymując rozwój chwastów oraz powodując ich deformację. Pierwsze efekty działania środka widoczne są po 14 dniach od wykonania zabiegu. Środek najlepiej działa na młode intensywnie rosnące chwasty.

TOSCANA TOP 75 WG charakteryzuje się selektywnością czynną, co oznacza, że zboża rozkładają środek na związki nieaktywne.

Środek można stosować na wszystkich typach gleb.

Susza lub ulewne opady deszczu występujące w trakcie lub wkrótce po zabiegu mogą obniżać skuteczność działania środka.

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

Zboża ozime – zabieg jesienią

Chwasty wrażliwe:	chaber bławatek, gwiazdnica pospolita, jasnota purpurowa, mak polny, maruna bezwonna, rumianek pospolity, samosiewy rzepaku, skrytek polny, tasznik pospolity, tobołki polne
Chwasty średnio wrażliwe:	fiólek polny, przetacznik perski, przytulia czepna

Zboża ozime – zabieg wiosną

Chwasty wrażliwe:	chaber bławatek, gwiazdnica pospolita, jasnota purpurowa, jasnota różowa, mak polny, maruna bezwonna, niezapominajka polna, ostrożeń polny, przetacznik polny, rdest ptasi, rdest powojowaty, rumian polny, samosiewy rzepaku, sporek polny, starzec zwyczajny, stulica psia, tasznik pospolity, tobołki polne
Chwasty średnio wrażliwe:	bodziszek drobny, bodziszek porożcinany, gorczyca polna, dymnica pospolita, fiólek polny, maruna bezwonna, przetacznik bluszczokowy, przetacznik perski, przytulia czepna, rumianek pospolity

Zboża jare

Chwasty wrażliwe:	chaber bławatek, dymnica pospolita, fiólek polny, gorczyca polna, gwiazdnica pospolita, jasnota purpurowa, komosa biała, mak polny, maruna bezwonna, przytulia czepna, rdest powojowaty, rumian polny, rumianek pospolity, samosiewy rzepaku, tasznik pospolity
Chwasty średnio wrażliwe:	przetacznik polny, przytulia czepna

STOSOWANIE ŚRODKA

Pszenica ozima, pszenżyto ozime, jęczmień ozimy, żyto ozime

W UPRAWIE ZBÓŻ OZIMYCH NA GLEBACH ZASADOWYCH W APLIKACJI JESIENNEJ DOPUSZCZA SIĘ STOSOWANIE ŚRODKA RAZ NA TRZY LATA.

Środek stosować:

- a) jesienią od fazy 3 liści do końca fazy krzewienia (BBCH 13-29)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 20 g/ha
Liczba zabiegów: 1

lub

- b) wiosną od fazy 3 liści do fazy liścia flagowego (BBCH 13-39)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 25 g/ha
Liczba zabiegów: 1

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Jęczmień jary, pszenica jara, ~~owies~~, pszenżyto jare

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 20 g/ha

Termin stosowania: wiosną od fazy 3 liści do fazy liścia flagowego (BBCH 13-39).

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

**STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH
I ZASTOSOWANIACH MAŁOObszarowych**

Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik

Pszenica twarda ozima, pszenica orkisz ozima, pszenica płaskurka ozima, pszenica samopsza ozima

W UPRAWIE ZBÓŻ OZIMYCH NA GLEBACH ZASADOWYCH W APLIKACJI JESIENNEJ DOPUSZCZA SIĘ STOSOWANIE ŚRODKA RAZ NA TRZY LATA.

Środek stosować:

- a) jesienią od fazy 3 liści do końca fazy krzewienia (BBCH 13-29)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 20 g/ha
Liczba zabiegów: 1

lub

b) wiosną od fazy 3 liści do fazy liścia flagowego (BBCH 13-39)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 25 g/ha

Liczba zabiegów: 1

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Żyto jare, ~~pszenżyto jare~~, pszenica twarda jara, pszenica orkisz jara, pszenica płaskurka jara, pszenica samopsza jara

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 20 g/ha

Termin stosowania: wiosną od fazy 3 liści do fazy liścia flagowego (BBCH 13-39).

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Miskant

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 25 20 g/ha

Termin stosowania: od fazy 2 do 4 liści (BBCH 12-14).

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Trawy – produkcja nasienna

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 25 20 g/ha

Termin stosowania: wiosną od fazy 3 liści do fazy liścia flagowego (BBCH 13-39).

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

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

Nie dotyczy

1. Strategia zarządzania odpornością

Środek zawiera substancję czynną z grupy sulfonilomocznika. Stosowanie po sobie herbicydów o tym samym mechanizmie działania może prowadzić do powstawania form odpornych chwastów. W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodzić z Dobrą Praktyką Rolniczą:

– postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecanym 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 nie satysfakcjonującym zwalczaniu chwastów,
 - w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub jego przedstawicielem.
2. Środka nie stosować:
- w okresie suszy,
 - na rośliny chore, uszkodzone lub mokre,
 - przed zbliżającymi się przymrozkami i deszczem,
 - podczas wiatru, stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
 - łącznie z nawozami stosowanymi nalistnie,
 - w zbożach z wsiewką lub z planowaną wsiewką,
3. Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

NASTĘPSTWO ROŚLIN

Środek nie stwarza zagrożenia dla roślin uprawianych następnie.

W przypadku konieczności likwidacji plantacji potraktowanej środkiem w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki nie ma przeciwwskazań do uprawy innych roślin.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić jej ilość.

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania po środku przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości.

Po wleciu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz mechanicznie wymieszać.

Przy dłuższej aplikacji lub po przerwie, ponownie wymieszać ciecz użytkową, którą należy zużyć w dniu przygotowania.

Opryskiwać z włączonym mieszadłem

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYIE APARATURY

Resztki cieczy użytkowej 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.

Z wodą użytą do mycia opryskiwacza należy postąpić tak, jak z resztkami cieczy użytkowej.

Ze względu na bardzo dużą wrażliwość niektórych roślin uprawnych nawet na znikome ilości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w innych roślinach uprawnych niż zalecane.

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 i odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

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 lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Zboża ozime i zboża jare i zastosowania małoobszarowe

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin i stawonogów niebędących celem działania środka konieczne jest wyznaczenie:

Zboża ozime i zastosowania małoobszarowe w dawce 25 g środka/ha

-5 m strefy ochronnej od terenów nieużytkowanych rolniczo lub,

-1 m strefy ochronnej z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% od terenów nieużytkowanych rolniczo.

Zboża ozime i zboża jare i zastosowania małoobszarowe w dawce 20 g środka/ha

- 5 m strefy ochronnej od terenów nieużytkowanych rolniczo, lub

-1 m strefy ochronnej z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 - 30°C.

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 razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

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

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 2 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Please refer to the reference list.

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

Please refer to the reference list.

List of data submitted by the applicant and not relied on

Please refer to the reference list.

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

Please refer to the reference list.