

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: MT-565SG-OR2-C

Product name(s): HAKSAR TOP 565 SG

Chemical active substance(s):

MCPA, 550 g/kg

Tribenuron methyl, 15 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland
(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 01/2021

MS Finalisation date: 06/12/2021

Version history

When	What
January 2021	First submission for product authorisation to zRMS.
02/2021	Dossier sent for evaluation to Merit Mark (PL)
August 2021	Correction on first submission for product
08/2021	zRMS finalised evaluation
December 2021	Final RR

Table of Contents

1	Details of the application	5
1.1	Application background	5
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorization decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	7
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	7
2.4.2	Standard phrases under Regulation (EU) No 547/2011	7
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	8
2.5	Risk management	8
2.5.1	Restrictions linked to the PPP	8
2.5.2	Specific restrictions linked to the intended uses	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorization decision and risk management	13
3.1	Physical and chemical properties (Part B, Section 2)	13
3.2	Efficacy (Part B, Section 3)	13
3.3	Efficacy data	13
3.3.1	Information on the occurrence or possible occurrence of the development of resistance	13
3.3.2	Adverse effects on treated crops	15
3.3.3	Observations on other undesirable or unintended side-effects	15
3.4	Methods of analysis (Part B, Section 5)	15
3.4.1	Analytical method for the formulation	15
3.4.2	Analytical methods for residues	15
3.5	Mammalian toxicology (Part B, Section 6)	16
3.5.1	Acute toxicity	16
3.5.2	Operator exposure	16
3.5.3	Worker exposure	16
3.5.4	Bystander and resident exposure	16
3.6	Residues and consumer exposure (Part B, Section 7)	17
3.6.1	Residues	17
3.6.2	Consumer exposure	22
3.7	Environmental fate and behaviour (Part B, Section 8)	22
3.7.1	Predicted environmental concentrations in soil (PEC _{soil})	22
3.7.2	Predicted environmental concentrations in groundwater (PEC _{gw})	22
3.7.3	Predicted environmental concentrations in surface water (PEC _{sw})	23
3.7.4	Predicted environmental concentrations in air (PEC _{air})	24
3.8	Ecotoxicology (Part B, Section 9)	24

3.8.1	Effects on terrestrial vertebrates	24
3.8.2	Effects on aquatic species	24
3.8.3	Effects on bees	25
3.8.4	Effects on other arthropod species other than bees.....	25
3.8.5	Effects on soil organisms	25
3.8.6	Effects on non-target terrestrial plants	25
3.8.7	Effects on other terrestrial organisms (Flora and Fauna).....	25
3.9	Relevance of metabolites (Part B, Section 10)	25
Appendix 1	Copy of the product authorization	26
Appendix 2	Copy of the product label	27
Appendix 3	Letter of Access	33
Appendix 4	Lists of data considered for national authorization.....	33

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 January 2021.

The information, data and assessments provided in Registration Report, Parts B includes assessment of data and information relating to HAKSAR TOP 565 SG where that data has not been considered in the EU review. Otherwise assessments for the safe use of HAKSAR TOP 565 SG have been made using endpoints agreed in the EU review of MCPA and Tribenuron-methyl.

1.1 Application background

The application is submitted for registration of plant protection product HAKSAR TOP 565 SG in Poland according to art. 33 of Regulation 1107/2009. The product has not been previously evaluated in any country from Central Zone of Europe according to Uniform Principles. The zRMS is Poland. The uses applied for spring and winter cereals (autumn and spring application). The application is also submitted of uses of the product HAKSAR TOP 565 SG on minor uses i.e.: durum wheat, spelt wheat, einkorn wheat, emmer wheat (autumn 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

The Applicant has conducted and submitted own studies on HAKSAR TOP 565 SG which are sufficient to evaluate of the product. No other studies/data were required and therefore no letter of access was submitted.

1.3 Justification for submission of tests and studies

All tests and studies for HAKSAR TOP 565 SG are submitted to meet the requirements of Regulation (EC) No. 284/2013. These studies are necessary to gain the authorisation.

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	MT-565SG-OR2-C
Product name in MS	HAKSAR TOP 565 SG
Authorization number	N/A
Function	herbicide
Applicant	CIECH Sarzyna S.A.
Active substance(s) (incl. content)	MCPA 550 g/kg Tribenuron-methyl 15 g/kg
Formulation type	SG
Packaging	HAKSAR TOP 565 SG will be commercially available in the following packages: <ul style="list-style-type: none">1 kg; 5 kg - HDPE or HDPE/LDPE or LDPE heat sealed, machine-molded bags, packed in printed cardboard boxes;

	<ul style="list-style-type: none"> • 10 kg ; 20 kg; 25 kg; 30 kg – HDPE or HDPE/LDPE or LDPE bags packed in three or four-layers paper bags; • 10 kg ; 20 kg; 25 kg; 30 kg – HDPE or HDPE/LDPE or LDPE bags are formed and welded from PE; • 1 kg; 5 kg; 10 kg ; 20 kg ; 25 kg and 30 kg– HDPE or HDPE/LDPE or LDPE heat sealed bags with printed label. • 1L - HDPE or HDPE/LDPE bottles • 3L, 5L, 10L, 20L - HDPE or HDPE/LDPE containers/canisters • 1L - PE/PA bottles • 2L, 3L, 5L, 10L – PE/PA (containers/canisters) <p>Professional user</p>
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: Haksar Top 565 SG contains two active substances with different mechanisms of action from different chemical families and has a broad spectrum of weed species to control. Mechanisms of action (Mode of action) of the two active substances fully complement each other and thanks to that the preparation has fast and strong action on redundant plants. It can be used in dose 1kg/ha in all winter and spring cereals (except spring triticale) in a wide range of cereal development stages BBCH 13-39 in autumn or spring application. Haksar Top 565 SG is highly effective against the most troublesome weeds in cereals. The number of weeds showing lower sensitivity to the tested herbicide is low and it is highly selective towards cereals. Haksar Top 565 SG in dose 1kg/ha (550g/ha of MCPA+15g/ha of Tribenuron-methyl) is intended for use in one application per season. The use of Haksar Top 565 WG provides high organizational and economic advantages in cereal cultivation, which confirms the advisability of its registration.

Residues: 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 HAKSAR TOP 565 SG 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.

Taking into account the approaching date of the re-evaluation of both active substances, it should be emphasized that after the re-evaluation it will be necessary to re-evaluate this documentation.

Fate & Behaviour: The evaluation of the application for HAKSAR TOP 565 SG resulted in the decision to grant the authorization in: uses 1-9. For alkaline soils the autumn application in winter cereals is acceptable if the formulation is used every third year.

Ecotoxicology: Uses applied for HAKSAR TOP 565 SG in: winter and spring cereals and grasses were authorised.

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:	Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1
-------------------------------	-----------------------------------------------------------------------------------------------------

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:	GHS05, GHS07, GHS09
Signal word:	Danger
Hazard statement(s):	H302 - Harmful if swallowed H315 - Causes skin irritation H317 - May cause an allergic skin reaction H318 - Causes serious eye damage H410 - Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P261 - Avoid breathing dust/spray. P280 - Wear protective gloves/ protective clothing/eye protection P302+P352 - IF ON SKIN: Wash with plenty of water P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing 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).
SPe 2	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 an unsprayed buffer zone of 5 m or 1m with 75% drift reduction to non-agricultural land.

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

2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
	Working wear during mixing, loading and application, gloves during mixing and loading and additionally eye protection (due to classification as Eye Dam.1)
Worker protection:	
-	-
Integrated pest management (IPM)/sustainable use:	
Mode of action (HRAC-group):	MCPA: O 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).
SPe 2	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 an unsprayed buffer zone of 5 m or 1 m with 75% drift reduction 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.
-	For use 1-9 To protect non target plants and non target arthropods respect 5 m or 1 m with 75% drift reduction to non-agricultural land.	-

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	MT-565SG-OR2-C / HAKSAR TOP 565 SG	Formulation type:	SG ^(a, b)	GAP date: January 2021
Active substance 1:	MCPA	Conc. of as 1:	550 g/kg ^(c)	
Active substance 2:	Tribenuron-methyl	Conc. of as 2:	15 g/kg ^(c)	
Safener:	N/A	Conc. of safener:	N/A ^(c)	
Synergist:	N/A	Conc. of synergist:	N/A ^(c)	
Applicant:	CIECH Sarzyna S.A.	Professional use:	<input checked="" type="checkbox"/>	
Zone(s):	central ^(d)	Non professional use:	<input type="checkbox"/>	
Verified by MS:	yes			

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop 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 – 23	a) 1 b) 1	n.a.	a) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha	200 / 400	n.a.	A
2	PL	Winter soft wheat (TRZAW), Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g	200 / 400	n.a.	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, 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		
										as/ha; tribenuron methyl 15 g as/ha			
3	PL	Winter barley (HORVW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha	200 / 400	n.a.	A
4	PL	Winter rye (SECCW), Winter triticale (TTLWI),	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha	200 / 400	n.a.	A
5	PL	Spring wheat (TRZAS), Oat (AVESA)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha	200 / 400	n.a.	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, 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		
Minor uses according to Article 51 (zonal uses)													
6	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) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g as/ha; tribenuron methyl 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
7	PL	Durum wheat (TRZDU), Spelt wheat (TRZSP), Spring rye (SECCS), Spring triticale (TTLWS), einkorn wheat (TRZMO), emmer wheat (TRZDI)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g as/ha; tribenuron methyl 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 uses. It is possible to register in Poland without an effectiveness test pursuant to Art 51 of the Regulation 1107/2009
8	PL	Miscanthus sp. (MISSS)	F	Annual dicotyledonous weeds	Broadcast - foliar	BBCH 12 -14	a) 1 b) 1	n.a.	a) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g as/ha; tribenuron methyl 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

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		
9	PL	Grasses grown for seeds	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 1,00 kg/ha; b) 1,00 kg/ha	a) MCPA 550 g as/ha; tribenuron methyl 15 g as/ha b) MCPA 550 g as/ha; tribenuron methyl 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

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

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

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 beige granules with characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable. It has no self-ignition temperature until 400°C. In aqueous solution, it has a pH value around 9.24 at 20°C. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PE bags, HDPE and PE/PA bottles. Its technical characteristics are acceptable for a water-soluble granules (SG) formulation. The intended concentration of use is 0.25% to 0.5%.

3.2 Efficacy (Part B, Section 3)

HAKSAR TOP 565 SG is a soluble granules (SG) containing 15 g/kg of Tribenuron methyl and 550 g/kg of MCPA 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 13-23) or in spring (BBCH 13-39) with recommended water volume 200-400 L/ha and maximum one application per crop/season.

The registration applies also the uses of product HAKSAR TOP 565 SG 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 147 trials investigating the minimum effective dose and the effectiveness of HAKSAR TOP 565 SG against weeds were implemented in 2016, 2017 and 2018. Those trials were undertaken in winter wheat, winter barley, winter rye, winter triticale, spring wheat, spring barley and oat.

Trials were located in the Maritime EPPO zone (Germany and United Kingdom, 67 trials) in, North-Eastern EPPO zone (Poland, 65 trials) and in the South-Eastern EPPO zone (Hungary and in Romania, 15 trials). All trials were carried out by officially recognized organisations, in accordance with the Principles of Good Experimental Practices (GEP).

Based on the submitted efficacy data package, it can be concluded that dose 1,0 kg/ha of HAKSAR TOP 565 SG effectively controlled targeted weeds, when compared with lower tested rates (0,8 kg/ha or 0,6 kg/ha) for which efficacy obtained was lower and less consistent. Therefore the dose of 1,0 kg/ha provided the optimum overall control and should be considered as effective against targeted weed species, for which activity of HAKSAR TOP 565 SG is claimed.

The efficacy of HAKSAR TOP 565 SG was investigated over 40 different weed species in all EPPO zones. Whatever the EPPO zone considered, application timing or crops, HAKSAR TOP 565 SG at 1,0 kg/ha (550 g/ha of MCPA + 15 g/ha of Tribenuron-methyl) 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 sp.*, *Papaver rhoeas*, *Tripleurospermum inodorum*, *Stellaria media*.

Consequently, it is justified to claim the registration of one application of HAKSAR TOP 565 SG at 1,0 kg/ha in autumn (BBCH 13-23) or spring (BBCH 13-39) on winter and 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

MCPA belongs to the Phenoxy-carboxylic-acid (HRAC group: O) chemical family and is a selective and systemic auxin growth regulator herbicide. It is absorbed by roots or leaves with a translocation and accumulation in vegetative shoots and roots (PPDB, 2018). This herbicide disrupts plant cell division, growth and differentiation of meristematic tissues in the newly forming stems and leaves, it affects protein synthesis and damages the vascular system (Grossmann and Mediation, 2003). Bending and twisting

of leaves and stems is observed almost immediately after application. Delayed symptom development includes malformed growth and tumours: misshapen leaves, stems and flowers and abnormal roots (Alberta Agriculture and Forestry, 2018). The effects associated with auxins help set them apart from other downwardly mobile herbicides (Prudue University, 2018).

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, some evidence of resistance has been shown and linked to the use of MCPA for the first time in 1979 (Sweden in cropland). Resistance have been then observed in several countries worldwide, twelve known broad-leaved weeds have developed a resistance against MCPA so far, and only 3 cases in Europe were recorded: *Cirsium arvense* (1979 – Sweden, 1985 – Hungary) and *Papaver rhoeas* (2016 – France). Only *Papaver rhoeas* has evolved MCPA resistant in cereals crops but with a cross-resistance to ALS-inhibitor which is the mode of action of Tribenuron-methyl.

Against tribenuron-methyl first evidence of resistance has been appeared time in 1987 in United States (Idaho) and cases of 43 broad-leaved weed species have been reported worldwide (Weed science, 2018). Already 14 weed species have evolved Tribenuron-methyl resistant in cereals crops among which 4 broad-leaved weed species (*Galium spurium*, *Kochia scoparia*, *Papaver rhoeas* and *Sinapis arvensis*) have developed cross-resistance to Synthetic Auxin herbicides (quinchlorac, dicamba, fluoxypyr and 2,4-D) which is the mode of action of MCPA.

Therefore, the risk of resistance development among broad-leaved weeds in cereals crops depends on the cropping systems and seem to be low for MCPA but could be high for Tribenuron-methyl particularly in wheat, winter wheat and spring barley. Thereby, it seems interesting to combine those two active substances to optimise the control of broad-leaved weeds in cereals crops.

HAKSAR TOP 565 SG combines two modes of action (ALS-inhibitor and Synthetic Auxin) what should reduce the risk of resistance development. However, because cross-resistance between herbicides with these modes of action have already occurred on some broad-leaved species in Europe, some guidelines should be used in order to prevent the resistance from appearing against this coformulation.

Resistance

MCPA

No confirmed resistance of dicotyledonous weeds to MCPA has been demonstrated in Poland, although resistant weed biotypes occurring in agricultural crops in Europe have been reported. A very cogent explanation of the applicant's MCPA status was cited.

Tribenuron-methyl

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.

Due to the occurrence of resistant weed biotypes in Poland, it is necessary to apply an appropriate antiresistant strategy for tribenuron-methyl.

The benefits of Haksar Top 565 SG (Tribenuron-methyl +MCPA) justify a policy on the use of herbicides based on these a.s. and allow it to be introduced and maintained on the market. This policy must be strictly defined and its principles widely available and applied by agricultural producers.

The applicant has presented in the label of Haksar Top 565 SG the relevant elements and data necessary to conduct an anti-resistance policy in accordance with the EPPO PP 1/213 guidelines (4).

3.3.2 Adverse effects on treated crops

A total of 114 selectivity trials investigating the adverse effects on treated crops (phytotoxicity, impact on yield and on quality parameters) of HAKSAR TOP 565 SG on treated plants were implemented in 2016 and 2017 in Maritime EPPO zone (Germany and United Kingdom), North-east EPPO zone (Poland) and South-east EPPO zone (Hungary and Romania). Furthermore, phytotoxicity of HAKSAR TOP 565 SG was assessed in 147 efficacy trials implemented from 2016 to 2018.

Irrespective of the EPPO climatic zone, in the majority of trials no phytotoxic symptoms were seen following application of HAKSAR TOP 565 SG at 0,6 – 1,0 kg/ha at efficacy trials and 1,0 kg/ha and 2,0 kg/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 HAKSAR TOP 565 SG, irrespective of the application timing or EPPO zone.

The dossier is accompanied by selectivity test reports numbered from 1-116. Report No. 72 was not attached.

Report No. 104 (U17106KO1) has no evaluation results. In this situation, 114 reports are assessed, not 116.

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 HAKSAR TOP 565 SG does not pose non acceptable risk for succeeding crops after 100 days from application.

If it is necessary to liquidate a plantation treated with the product as a result of damage to plants by frosts, diseases or pests after performing pre-sowing cultivation, other plants can be grown.

As a result of the risk assessment prepared in accordance to the EPPO guideline PP 1/256 HAKSAR TOP 565 SG 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 HAKSAR TOP 565 SG on beneficial or other non-target organisms.

3.4 Methods of analysis (Part B, Section 5)

The methods were successfully evaluated and meet the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance document SANCO/3030/99.

3.4.1 Analytical method for the formulation

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

The content of the relevant impurities of free phenols in the formulation was determined by UV spectrophotometry.

The analytical methods were fully validated and meet the EU criteria with respect the specificity, 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 MCPA and Tribenuron methyl in food of plant and animal origin, soil, water and air. All this

analytical methods are active substance data and were provided in the EU review of MCPA and Tribenuron methyl.

However, additional data on methods/validation in plants for MCPA and Tribenuron methyl have been provided. The analytical methods were fully validated and meet the EU criteria with respect the specificity, linearity, accuracy and precision according to the requirements given in the guidance documents SANCO/3029/99 rev. 4, 11/07/2000, SANCO/825/00 rev. 8.1, 16/11/2010. All data are considered adequate.

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 and provided that the PPE/ risk mitigation measures is 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.

All justification of estimation of the toxicity of the HAKSAR TOP 565 SG is presented in Appendix 2 of Part B, Section 6.

3.5.2 Operator exposure

Using EFSA GD Exposure Calculator at the 75th percentile, operator exposures were estimated for maximum application rates of HAKSAR TOP 565 SG to cereals and grasslands and against the AOEL agreed in the EU review of MCPA and Tribenuron-methyl. Results show that the risk for the operator using HAKSAR TOP 565 SG with vehicle mounted sprayer is acceptable when working wear during mixing, loading and application and gloves during mixing, loading of the product is applied.

Additionally due to classification Eye Damage 1 eye protection should be worn.

3.5.3 Worker exposure

The results of the exposure estimations based on EUROPOEM II and EFSA calculator show that the use of HAKSAR TOP 565 SG according to the list of intended uses presented in GAP Table, causes no health risk for the worker because the calculated exposure level to MCPA and Tribenuron-methyl is below of the values of AOEL for this active substances (assuming no PPE is used -worker wears only the work wear).

3.5.4 Bystander and resident exposure

The incidental short-time exposure of bystander and resident (children and adult) to MCPA and Tribenuron-methyl contained in the formulation HAKSAR TOP 565 SG causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table and when in case use in cereals the drift-reduction nozzles or 5 m buffer strip is applied.

Combined exposure

The product is mixture of two active substances.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially,. First, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

The Hazard Index is < 1. Thus, combined exposure to all active substances in HAKSAR TOP 565 SG is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required..

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

The use of product HAKSAR TOP 565 SG does not lead to unacceptable risk for consumer when applied according to the recommendations.

3.6.1 Residues

Tribenuron methyl

Critical GAP for HAKSAR TOP 565 SG on cereals (wheat, triticale, barley, rye): 1 appl., max. BBCH-39, max application rate: 15 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 HAKSAR TOP 565 SG.

Critical GAP for HAKSAR TOP 565 SG on Miscanthus sp. (MISSS): 1 appl., max. BBCH-14, max application rate: 15 g a.s/ha, PHI- not applicable

Critical GAP for HAKSAR TOP 565 SG on grasses grown for seeds: 1 appl., max. BBCH-39, max application rate: 15 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 HAKSAR TOP 565 SG. 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=4, field trials in Poland, Hungary, Germany 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). 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, oat 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 HAKSAR TOP 565 SG 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 HAKSAR TOP 565 SG 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.

MCPA

EU GAP for cereals (Review report for the active substance MCPA, SANCO/4062/2001-final 11 July 2008): Winter and spring cereals: 1 appl., Spring, before first node detectable, appl. rate 1.8 kg a.s./ha

GAP proposed for HAKSAR TOP 565 SG:

Cereals (wheat, barley, rye, oats): 1 appl., appl. rate 550 g a.s. /ha, max BBCH 39

The EU critical GAP for MCPA covers GAP proposed for HAKSAR TOP 565 SG.

Stability of residues

After 18 months of storage at a temperature below –18°C, residues of MCPA in supplemented samples of cereal plants, grain and straw were all found above 70% of the initial level. Residues can thus be considered as stable in the described storage conditions over the storage period. (DAR, Wasser C., 2002)

Storage stability studies were evaluated at EU level during the Annex inclusion process and were considered to be acceptable. The studies demonstrated that residues of MCPA are stable when stored under freezer condition for at least 18 months in cereals and for at least 3 months in muscle, milk, fat, kidney and liver. The stability of residues in sample extracts has been confirmed by the recovery of the analytical methods.

Metabolism in plants (MCPA end points, August 2004)

Plant groups covered Wheat, maize, beans

Rotational crops covered Do not submitted at GAP 1.8 kg/ha

Plant residue definition for monitoring MCPA

Plant residue definition for risk assessment MCPA

Conversion factor from enforcement to RA Not applicable

Metabolism studies in plants and animals were evaluated in DAR for MCPA (March 2001). Results from the metabolism studies in wheat showed a rapid degradation of MCPA via compound of no toxicological importance and no residues were found at harvest in edible parts of plant origin food.

Nature of residue in rotational crops

MCPA addendum to the DAR (2003):

Soil ¹⁴C-residue levels declined from 0.276 (Day 0) to 0.045 mg/kg (Day 582) over the duration of the study. A half-life value was calculated and found to be 63 days under the experimental conditions.

All lettuce samples from the 365-day planting were below the limit of detection (limit of detection 0.013 mg/kg) and had a total residue level below 0.05 mg/kg.

There were no residues detected in turnip samples at or above the limit of detection (< 0.013 mg/kg).

Detectable residues were found in the barley forage and straw samples from the 30-day planting and the straw samples from the 120-day planting but all were less than 0.05 mg/kg. In all other samples no residues were detectable (< 0.013 mg/kg).

The levels of total ¹⁴C-residues in the rotational crop samples were all less than 0.05 mg/kg.

Due to the very low residue levels in the crop samples, metabolite identification work was not feasible. No detectable ¹⁴C-residues were found in the rotational crop and soil samples from the untreated plot.

In the literature (Fryer and Kirkland; 1970) some experiments had already confirmed that MCPA, when used at the recommended rate, is unlikely to have any injurious effect on the capacity of soil to product healthy crops. In this reference possible long-term effects of repeated applications of MCPA were examined on one soil type.

Nature of residues in processed commodities

MCPA addendum vol.3 B6 (October 2003): *Based on results from residue trials conducted to date, no MCPA residues are expected at or above the limit of detection. It is therefore unlikely that MCPA resi-*

dues will be detected in processed fractions such as flour or bread. Therefore, no study has been conducted regarding the effects of industrial processing and household preparation on the nature and magnitude of MCPA residues.

Metabolism in livestock

Animals covered *hens, lactating goats*
Animal residue definition for monitoring *MCPA*
Animal residue definition for risk assessment *MCPA*
Conversion factor *Not applicable*
Metabolism in rat and ruminant similar *Yes*
Fat soluble residue *Yes*

Results from the metabolism studies in animals showed that MCPA is rapidly excreted (above 99%), within 24 hours.

The residue definition according to the current regulation (Reg. (EU) 491/2014) for plants is MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) and for animal products is MCPA, MCPB and MCPA thioethyl expressed as MCPA.

Magnitude of residues

Residue trials were presented in DAR for MCPA (March 2001) and are adequate. Residues of MCPA in cereals are below current MRL set as 0.2 mg/kg in accordance with current Commission Regulation (EU) No 491/2014 of May 2014.

In addition, the Applicant submitted additional studies (n=4, field trials in Poland, Hungary, Germany and UK) of magnitude the MCPA 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). Results from tree studies indicate the absence of MCPA residues in wheat grain above the detection limit (0.005 mg/kg), in one study residues were at the level 0.0137 mg/kg (below LOQ). 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 HAKSAR TOP 565 SG is 39.

Risk assessment

No concern for the consumer was identified, the highest TMDI was 16 % of the ADI (highest contributor to MS diet was milk– 6%, max 2% ADI for wheat), and the highest IESTI 16 % of the ARfD (bovine liver).

The long-term and short-term intake of MCPA residues are unlikely to present a public health concern.

Conclusion

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

The Applicant shall provide analytical method and 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 HAKSAR TOP 565 SG 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.

Taking into account the approaching date of the re-evaluation of both active substances, it should be emphasized that after the re-evaluation it will be necessary to re-evaluate this documentation.

3.6.2 Consumer exposure

The chronic consumer risk assessment was carried out using the EFSA PRIMo model. The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. A long term intake of residues of MCPA and Tribenuron methyl is unlikely to present a public health concern.

The acute risk assessment for MCPA and Tribenuron methyl was based on the ARfD, no exceedance of the ARfD/ADI was identified. No acute risk is expected from the consumption of the crops treated according to the intended uses.

The proposed uses of MCPA and Tribenuron methyl in the formulation HAKSAR TOP 565 SG do not represent unacceptable acute and chronic risks for the consumer.

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

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

The PEC values of HAKSAR TOP 565 SG, MCPA, tribenuron-methyl and its metabolites in soil have been assessed with the ESCAPE model (version 2.0), 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 MCPA (SANCO/4062/2001– final of 11/07/2008) and tribenuron-methyl (EFSA Journal 2017;15(7):4912).

Additional, the PEC_{soil} values were calculated for formulation.

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

In accordance with requirements, calculations of the predicted environmental concentration in groundwater (PEC_{GW}) of active substances and relevant metabolites were submitted taking into account the highest application rates of the plant protection product.

The predicted environmental concentrations in groundwater (PEC_{GW}) of MCPA have been assessed with a tiered approach. According to „Review Report” for MCPA (SANCO/4062/2001– final of 11/07/2008), no significant metabolites were found. 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.

Calculations of the predicted environmental concentrations of MCPA, tribenuron-methyl and metabolites of tribenuron-methyl in groundwater were performed for recommended uses (winter and spring cereals) of HAKSAR TOP 565 SG taking into account the maximum recommended rate of the product. Also, the minor uses (grass) were considered in PEC_{gw} calculation. The predicted environmental concentrations (PEC) of MCPA, tribenuron-methyl and metabolites of tribenuron-methyl in groundwater have been determined for application of HAKSAR TOP 565 SG 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.

Tribenuron methyl. For the intended use of HAKSAR TOP 565 SG 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 considered at the maximum rate to winter cereals (autumn application) the results showed that PEC_{gw} of tribenuron-methyl in all FOCUS scenarios was $< 0.1 \mu\text{g/L}$.** 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 summarised in Section 8 of the dRR.

The simulation runs were conducted for an annual application rate of the substance tribenuron-methyl of 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 µg/L for all scenarios with all models. In addition, PEC_{gw} for the metabolites M2 and IN-R9805 were always < 0.1 µg/L.

Grass and Miscanthus. Based on Tier 2 modelling results and annual application rate of the substance tribenuron-methyl of 15 g a.s./ha, the maximum PEC_{gw} values for active substance were below the trigger value of 0.1 µg/L.

The information concerning the environmental metabolites IN-L5296, IN-A4098 and IN-00581 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 ground-water).

MCPA. All simulations were carried out in accordance with proposed intended use of formulation. For active substance the pH dependence approach was considered

A tiered approach was taken into consideration: Tier 1: no pH dependence and Tier 2: pH dependence – acidic, neutral and alkaline soils.

The maximum PEC_{gw} values for MCPA in all scenarios were below the trigger value of 0.1 µg/L.

Taking into account performed calculations it can be concluded that the results of PEC_{gw} for MCPA, tribenuron-methyl as well as for metabolites tribenuron-methyl in comparison with the regulatory threshold of 0.1 µg/L indicate an acceptable risk for all scenarios considered.

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 the highest application rate 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 substances and metabolites listed in the „Review Report” (SANCO/4062/2001– final of 11/07/2008) for MCPA and „EFSA Journal 2017;15(7):4912, Conclusion on the peer review of the pesticide risk assessment of the active substance Tribenuron-methyl” for Tribenuron methyl.

MCPA

The calculation of the predicted environmental concentrations of MCPA and in surface waters and water sediments were carried out taking into consideration the highest recommended application rate (550 g a.s./ha) of HAKSAR TOP 565 SG and relevant FOCUS scenarios, in case of Step 3 approach. During degradation studies in soil no significant metabolites were found. Thus, no predicted environmental concentrations in surface water and sediment for metabolites were calculated. The initial, short-term and long-term (actual and average time-weighted) values of PEC_{sw} and PEC_{sed} were calculated for parent following the FOCUS SW scheme up to Step 4 using the following programs: STEPS 1-2 in FOCUS v.3.2, SWASH v.5.3, PRZM v4.3.1, MACRO v5.5.4, TOXSWA v5.5.3 and SWAN v.5.0.1. The highest values of PEC_{sw} were used to determine the risk factors for aquatic organisms.

Tribenuron methyl

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 v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5.3 and SWAN v.5.0.1. The calculation of the predicted environmental concentrations of tribenuron methyl and its metabolites in surface water and sediment were carried out taking into consideration the highest recommended application rate of HAKSAR TOP 565 SG and relevant FOCUS scenarios. Moreover, 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. 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.

The mitigation measures were proposed using SWAN and VFSmod models. The final decision will be made in Section 9.

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

Based on summary of atmospheric degradation and behaviour of MCPA it can be concluded that MCPA has low volatility and low stability in the atmosphere. The risk of atmosphere pollution by above active substance following the application with MT-565SG-OR2-C is low. Therefore, there was no need to calculate PEC in 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 MCPA and Tribenuron-methyl, the risk of atmospheric pollution of both active substances following the use of HAKSAR TOP 565 SG is low.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Risk assessment for birds

The risk assessment performed for birds indicate acceptable acute and long-term exposed to MCPA and tribenuron methyl following application of HAKSAR TOP 565 SG acc. to intended GAP.

Mixture toxicity indicated acceptable risk due to the use of HAKSAR TOP 565 SG.

Risk assessment for mammals

Higher refinement was needed for both substances and weight of evidence was performed by zRMS for uses of HAKSAR TOP 565 SG in grasses due to the mixture toxicity.

The risk assessment performed for mammals indicate acceptable acute and long-term risk to birds and mammals exposed to MCPA and tribenuron methyl following application of HAKSAR TOP 565 SG acc. to intended GAP.

Birds and mammals

As the active substances have 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 MCPA and tribenuron-methyl).

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

3.8.2 Effects on aquatic species

Based on PEC/RAC calculations, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses in spring and winter cereals (autumn and spring application), and on minor for

HAKSAR TOP 565 SG.

For Poland the relevant scenarios are D3, D4 and R1 only, no unacceptable risk is indicated following the HAKSAR TOP 565 SG application. Thus, none mitigation measures are required on the label.

3.8.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

The acute risk assessments for the active substances as well as for the formulated product HAKSAR TOP 565 SG with Hazard Quotients well below the trigger for acceptability of effects indicate an acceptable risk for bees exposed in accordance with the intended uses in spring and winter cereals (autumn and spring application), and on minor uses according to the proposed GAP.

Therefore, a low risk to bees is expected from the application of HAKSAR TOP 565 SG and no mitigation measures are required.

3.8.4 Effects on other arthropod species other than bees

The risk assessment was conducted according to the ESCORT 2 Guidance Document (2000) and the Guidance Document on Terrestrial Ecotoxicology (2002).

Based on results obtained for MT-565SG-OR2-C in laboratory studies on *T. pyri* and *A. rhopalosiphi* the 'in-field' and “off-field” HQ values was below the trigger value of 2, indicating that HAKSAR TOP 565 SG poses an acceptable risk to non-target arthropods in both in-field and off-field areas without the need for risk mitigation measures.

3.8.5 Effects on soil organisms

Acute and chronic risk to earthworms arising from the application of HAKSAR TOP 565 SG according to the intended GAP uses can be excluded as the trigger values of 10 for acute risk and 5 for long-term risk were exceeded by far.

Additionally, performed long-term risk assessment for collembola and predatory mites indicates that TER_{lt} is above the trigger value of 5, indicating acceptable risk to soil organisms (other than earthworms) from the proposed uses of HAKSAR TOP 565 SG.

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 HAKSAR TOP 565 SG and relevant metabolites of Tribenuron methyl.

No risk mitigation measures are required.

3.8.6 Effects on non-target terrestrial plants

For the proposed use of HAKSAR TOP 565 SG, based on the highest application rate the risk for non-target plants in the off-crop area is indicated to be acceptable taking too consideration probabilistic approach with following mitigation measures:

- 1 m and use of 75% drift reducing technology or,
- 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 PEC_{gw} values for metabolites of active substance are in accordance with PELMO and

PEARL PECgw assessment (Section 8).

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

Tribenuron-methyl:

Metabolites IN-00581, IN-A4098 and IN-L5296 are predicted to occur in groundwater at concentrations above 0.1 µg/L and therefore the assessment of the relevance of these metabolites were performed according to the EC guidance document SANCO/221/2000 –rev.10. Toxicological studies on metabolites IN-A4098 and IN-L5296 supporting the lack of genotoxic potential were submitted. These studies were evaluated and accepted during evaluation of the product TOSCANA TOP 75 WG (Product code T-75WG-OR2C).

The outcome of the assessment shows that metabolites IN-00581, IN-A4098 and IN-L5296 can be considered to be non-relevant according to the EC guidance document SANCO/221/2000 –rev.10.

The relevance assessment of the metabolites is presented in Part B, Section 10.

Appendix 1 Copy of the product authorization

Not applicable. First submission for product authorization in MS country.

Appendix 2 Copy of the product label

Uwagi do etykiety:

Fizykochemia – zmieniono zapis o przechowywaniu środka w temperaturze 0 – 30°C.

Toksykologia – brak uwag do etykiety.

Pozostałości – dodano zapis, że trawa traktowana środkiem nie może być przeznaczona do skarmiania zwierząt.

Los i zachowanie w środowisku – usunięto zwrot P273, dodano zwroty P391 i P501. Dodano informację, że „w uprawie zbóż ozimych na glebach zasadowych w aplikacji jesiennej dopuszcza się stosowanie środka raz na trzy lata.”

Ekotoksykologia – wyznaczono strefę ochronną dla organizmów wodnych o szerokości 1 m od zbiorników i cieków wodnych. W celu ochrony roślin i stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy buforowej w odległości 5 m od terenów nieużytkowanych rolniczo lub wyznaczenie strefy buforowej 1 m z równoczesnym zastosowaniem technik redukujących znoszenie na poziomie 75%.

Skuteczność działania – zmieniono treść etykiety w akapicie „Działanie na chwasty”.

Załącznik do zezwolenia MRiRW nr R - z dnia

Posiadacz zezwolenia:

CIECH Sarzyna S.A., ul. Chemików 1, 37-310 Nowa Sarzyna, tel.: +48 17 24 07 111, fax: +48 17 24 07 122, e-mail: sarzyna@ciechgroup.com, www.ciechagro.pl

HAKSAR TOP 565 SG


Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

MCPA (związek z grupy fenoksykwasów karboksylowych) - **550 g/kg (55 %)**

Tribenuron metylowy (związek z grupy pochodnych sulfonilomocznika) - **15 g/kg (1,5 %)**

Zezwolenie MRiRW nr R - z dnia

	
Niebezpieczeństwo	
H302 H315 H317 H318 H410	Działa szkodliwie po połknięciu. Działa drażniąco na skórę. Może powodować reakcję alergiczną skóry. Powoduje poważne uszkodzenie oczu. 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.
P261 P280	Unikać wdychania pyłu / rozpylonej cieczy. Stosować rękawice ochronne/odzież ochronną/ ochronę oczu/ochronę twarzy.

P302+P352 P333+P313	W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody z mydłem. W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do podmiotu uprawnionego do utylizacji.

OPIS DZIAŁANIA

HAKSAR TOP 565 SG jest herbicydem selektywnym o działaniu układowym, w formie granul rozpuszczalnych w wodzie, stosowanym nalistnie, przeznaczonym do powschodowego zwalczania rocznych chwastów dwuliściennych w zbożach jarych i ozimych.

Zgodnie z klasyfikacją HRAC substancja czynna MCPA zaliczana jest do grupy O, natomiast tribenuron metylowy do grupy B.

DZIAŁANIE NA CHWASTY

Środek jest pobierany głównie poprzez liście chwastów, a następnie szybko przemieszczanym w roślinie, powodując jej deformację, zahamowanie wzrostu i zamieranie. Najskuteczniej zwalcza chwasty znajdujące się we wcześniejszych fazach rozwojowych – siewki, rozetki. Pogoda ciepła i sprzyjająca rozwojowi roślin wzmacnia działanie chwastobójcze środka.

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

Zboża ozime – zabieg jesienią

Chwasty wrażliwe:	chaber bławatek, gwiazdnica pospolita, jasnota purpurowa, jasnota różowa, mak polny, maruna bezwonna, niezapominajka polna , rumian polny, rumianek pospolity, samosiewy rzepaku, skrytek polny, stulisz lekarski , 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, mak polny, maruna bezwonna, przetacznik bluszczykowy, przetacznik polny, rumian polny, samosiewy rzepaku, sporek polny , tasznik pospolity, tobołki polne
Chwasty średnio wrażliwe:	dymnica pospolita , fiólek polny, niezapominajka polna, przetacznik perski, przytulia czepna, rumianek pospolity

Zboża jare

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

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.

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha

Termin stosowania: środek stosować:

a) Jesienią, od rozwinięcia trzeciego liścia do fazy 3 rozkrzewień (BBCH 13-23)

lub

b) wiosną, od rozwinięcia trzeciego liścia do fazy liścia flagowego (BBCH 13-39).

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Jęczmień jary, pszenica jara, owies

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha

Termin stosowania: środek stosować wiosną, od rozwinięcia trzeciego liścia 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

Pszemica twarda ozima, Pszemica orkisz ozima, pszemica plaskurka ozima, pszemica 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 fazy 3 rozkrzewień (BBCH 13-23)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha

Liczba zabiegów: 1

lub

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

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 kg/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: 1,0 kg/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: 1,0 kg/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: 1,0 kg/ha

Termin stosowania: 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

UWAGA: Trawa traktowana środkiem nie może być przeznaczona na paszę.

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 mieszankę 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,
 - w temperaturze poniżej 10°C i powyżej 25°C, - w okresie gdy temperatura nocą jest niższa niż 5°C,
 - przed zbliżającymi się przymrozkami i deszczem,
 - podczas wiatru, stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.
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

W przypadku konieczności likwidacji plantacji potraktowanej środkiem w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki/ po wykonaniu uprawy przedsiewnej można uprawiać zboża i kukurydzę.

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 wlewniu 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, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin 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.

Uprawa zbóż i uprawy małoobszarowe

W celu ochrony wód podziemnych w uprawie zbóż ozimych na glebach zasadowych w aplikacji jesiennej dopuszcza się stosowanie środka raz na trzy lata.

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 strefy buforowej w odległości 5 m od terenów nieużytkowanych rolniczo lub wyznaczenie strefy buforowej 1 m z równoczesnym zastosowaniem technik redukujących znoszenie na poziomie 75%.

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 – 2230°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 3 Letter of Access

The letter of access was submitted directly to MoA.

Appendix 4 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.