FINAL REGISTRATION REPORT

Part B

Section 1: Identity
Section 2: Physical and chemical properties
Section 4: Further information

Detailed summary of the risk assessment

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

CORE ASSESSMENT

Applicant: CIECH Sarzyna S.A.

Submission date: 1/2021

MS Finalisation date: 06/12/2021

Version history

When	What
January 2021	First submission for product authorization 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

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Evaluator comments:
The text highlighted in grey was provided by the evaluator.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name:	CIECH Sarzyna S.A.
Address:	ul. Chemików 1, 37-310 Nowa Sarzyna, Poland
Contact:	xxxxxxxxxxxx
Telephone number:	+xxxxxxxxxxxx
Fax:	+xxxxxxxxxxxxxx
E-mail:	xxxxxxxxxxxxx

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 MCPA

MCPA (EU agreed minimum purity) min. 930 g/kg

No impurities of toxicological/ ecotoxicological concern are identified in the active substance.

Information relating to the active substance and impurities is confidential information and therefore all details are included in Part C (confidential information).

1.2.3.2 Tribenuron-methyl

Tribenuron-methyl (EU agreed minimum purity) min. 950 g/kg

No impurities of toxicological/ ecotoxicological concern are identified in the active substance.

Information relating to the active substances and impurities is confidential information and therefore all details are included in Part C (confidential information).

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name:	HAKSAR TOP 565 SG
Company code number:	MT-565SG-OR2-C

1.4 Detailed quantitative and qualitative information on the composition of the

preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content (%w/w)
MCPA 4-chloro-o-tolyoxyacetic acid	550 g/kg	525-575 g/kg	561 g/kg	56.1 %
Tribenuron-methyl	15 g/kg	11.25-18.75 g/kg	15.38 g/kg	1.54 %

* Based on the minimum purity of MCPA 980 g/kg and Tribenuron-methyl 975 g/kg

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Not applicable No safener was used in formulation	-	-	-	-

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Not applicable. Non relevant impurities were identified EU level assessment.	-

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on MCPA

Type	Name/Code Number
ISO common name	MCPA
CAS No.	94-74-6
EC No.	202-360-6
CIPAC No.	2

Table 1.4-5: Information on Tribenuron-methyl

Type	Name/Code Number
ISO common name	Tribenuron-methyl
CAS No.	101200-48-0
EC No.	401-190-1
CIPAC No.	546.201

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Table 1.4-5: Information on safeners/ synergists / co-formulant

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Water soluble granules [Code: SG]

1.6 Function (KCP 1.6)

herbicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

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 a 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%.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

No classification and labelling with respect to physical and chemical properties is needed.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No hazard and safety phrases are needed for this section.

Compliance with FAO specifications:

The product HAKSAR TOP 565 SG complies with FAO specifications.

Formulation used for tests

All the product samples used in the tests presented to support the present dossier were equivalent to the formulation described in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	EPA OPPTS 830.6302, EPA OPPTS 830.6303 EPA OPPTS 830.6304 and Polish Pharmacopoeia VI	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	Cylindrical beige granules of characteristic odour	Y	BF-109/16 Part I	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	The tested material does not have explosive properties according to the criteria of EEC A.14 method.	Y	BW-41/16	Accepted
Oxidizing properties (KCP 2.2.2)	EEC A.17	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	The tested material has no oxidizing properties according to A.17 method.	Y	BC-27/17	Accepted
Flash point (KCP 2.3.1)	Not applicable. MCPA+Tribenuron metyl 565 SG is a solid formulation. Determination of flash point is applicable only for liquid substances whose vapours can be ignited by ignition sources.					Not applicable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flammability (KCP 2.3.2)	EEC A. 10	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	The tested material is not highly flammable in accordance with test A.10. criteria.	Y	BC-27/17	Accepted
Self-heating (KCP 2.3.3)	EEC A.16	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	The tested material does not have the relative self-ignition temperature in accordance with test A.16. criteria.	Y	BC-27/17	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	Not applicable. MCPA+Tribenuron metyl 565 SG is a solid.					Not applicable
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	pH = 9.24 at 20 ºC (pH of 1% water solution).	Y	BF-109/16 Part I	Accepted
Viscosity (KCP 2.5.1)	Not applicable. MCPA+Tribenuron metyl 565 SG is a solid.					Not applicable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (KCP 2.5.2)	Not applicable. MCPA+Tribenuron metyl 565 SG is a solid.					Not applicable
Relative density (KCP 2.6.1)	Not applicable. MCPA+Tribenuron metyl 565 SG is a solid.					Not applicable
Bulk density (KCP 2.6.2)	CIPAC MT 186	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	The average measured pour density was 0.63 g/ml and the tap density equaled 0.68 g/ml.	Y	BF-109/16 Part I	Accepted
Storage Stability after 14 days at 54º C (KCP 2.7.1)	According to FAO specification for Tribenuron-methyl this substance could be sensitive to higher temperatures therefore the accelerated storage test for formulation was carried out at 35 °C for 12 weeks (please see point KCP 2.7.2).					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.3 HPLC UV/Vis	MCPA+Tribenuron metyl 565 SG containing 561 g/kg of MCPA and 13.1 g/kg of tribenuron-methyl Batch no 2/19 Production date: 06.2019	**After storage at (35±2) °C for 12** weeks in glass beaker the product was still cylin-drical grey - beige granules with characteristic odour Detailed results after accelerated storage stability procedure are presented below The content of the active substance MCPA: Before storage: 53.52% (535.2 g/kg) After storage: 53.03 % (530.3 g/kg) The content of the active substance tribenuron methyl: Before storage: 1.25% (12.5 g/kg)	Y	BF-25/19	Not accepted. Tribenuron is below the FAO limits.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After storage: 0.82 % (8.2 g/kg)			
	CIPAC MT 75.3		pH value of 1% dispersion: Before storage: 9.28 After storage: 9.39			
	CIPAC MT 179.1		Before storage: 0.42% after 5 min and 0.00% after 24 h After storage 0.47% after 5 min and 0.00% after 24 h			
	CIPAC MT 170		Dry sieve test: Before storage: over 3350 µm 0.01% 2000 – 3350 µm 0.06% 1000 – 2000 µm 77.82% 500 – 1000 µm 21.76% 250 – 500 µm 0.11% 125 – 250 µm 0.07% 75 – 125 µm 0.05% Under 75 µm 0.14% After storage: over 3350 µm 0.09% 2000 – 3350 µm 0.07% 1000 – 2000 µm 73.21% 500 – 1000 µm 25.98% 250 – 500 µm 0.36% 125 – 250 µm 0.07% 75 – 125 µm 0.07% Under 75 µm 0.18%			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 171 CIPAC MT 178.2 CIPAC MT 172		The content of dust: Before storage: 0.8mg (0.00%) After storage: 0.7 mg (0.00%) Attrition resistance: Before storage: 99.81% After storage: 99.85% Flowability was 100% after accelerated storage			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.3 HPLC UV/Vis CIPAC MT 75.3 CIPAC MT 47.3	MCPA+Tribenuron metyl 565 SG containing 550 g/kg g/kg of MCPA and 15 g/kg of tribenuron-methyl Batch no 1/2020 Production date: 07.2020	**After storage at (30±2) °C for 18** weeks in glass beaker the product was still cylin-drical light - beige granules with characteristic odour Detailed results after accelerated storage stability procedure are presented below: The content of the active substance MCPA: Before storage: 55.15% (551.5 g/kg) After storage: 55.15% (551.5 g/kg) The content of the active substance tribenuron methyl: Before storage: 1.48% (14.8 g/kg) After storage: 1.47% (14.7 g/kg) pH value of 1% dispersion: Before storage: 9.30 After storage: 9.31 Persistance of foaming (0.25% water suspension,	Y	BF- 11/21	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			standard water CIPAC D): After 1 min – 18ml After 12min – 17ml Persistance of foaming (0.5% water suspension, standard water CIPAC D): After 1 min – 70ml After 12min – 37ml			
	CIPAC MT 179.1		Before storage: 0.00% after 5 min and 0.00% after 24 h After storage 0.0% after 5 min and 0.00% after 24 h			
	CIPAC MT 170		Dry sieve test Before storage: fraction > 3350 µm 0.00% fraction 2000 - 3350 µm 0.15% fraction 1000 - 2000 µm 99.07% fraction 500 - 1000 µm 0.67% fraction 250 - 500 µm 0.01% fraction 125 - 250 µm 0.00% fraction 75 - 125 µm 0.07% fraction < 75 µm 0.05% After storage: fraction > 3350 µm 0.00% fraction 2000 - 3350 µm 0.05% fraction 1000 - 2000 µm 98.82% fraction 500 - 1000 µm 1.04% fraction 250 - 500 µm 0.02% fraction 125 - 250 µm 0.01% fraction 75 - 125 µm 0.05% fraction < 75 µm 0.03%			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 178.2 CIPAC MT 171.1 CIPAC MT 172.1		Attrition resistance: Before storage: 99.85% After storage: 99.96% The content of dust: Before storage: 1.5 mg (0.00%) After storage: 1.1 mg (0.00%) Flowability was 100% after accelerated storage			
Minimum content after heat stability testing (KCP 2.7.3)	CIPAC MT 46.3	MCPA+Tribenuron metyl 565 SG containing 561 g/kg of MCPA and 13.1 g/kg of tribenuron-methyl Batch no 2/19 Production date: 06.2019	The content of the active substance MCPA: Before storage: 53.52% (535.2 g/kg) After storage: 53.03 % (530.3 g/kg) The content of the active substance tribenuron methyl: Before storage: 1.25% (12.5 g/kg) After storage: 0.82 % (8.2 g/kg)			Not required The study was rejected by zRMS anyway.
Effect of low temperatures on stability (KCP 2.7.4)	Not applicable. MCPA+Tribenuron metyl 565 SG is a solid.					Not applicable
Ambient temperature shelf life (KCP 2.7.5)	GIFAP Technical Monograph No. 17	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	After storage at 20°C for 2 years in PE bags physical state, colour and odour of the tested material have not changed. The shape and the colour of the PE packages were stable. The minor mass change of the packages has no effect in the physicochemical properties of the tested preparation.	Y	BF-109/16 Part I BF-109/16 Part IV	Accepted A shelf life of two year is accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	HPLC UV		The content of the active substance: MCPA Before study: 55.63% (556.3 g/kg) After storage: 55.43% (554.3 g/kg) Tribenuron-methyl Before study: 1.35% (13.5 g/kg) After storage: 1.29% (12.9 g/kg) Content of free phenols: Before study: 0.775 g/kg After storage: 0.734 g/kg			
	CIPAC MT 75		pH value of 1% water solution: Before study: 9.24 After storage: 9.80			
	CIPAC MT 179		Dilution stability test: Before study: – after 5 minutes – 0.75 % – after 18 hours was 0.00 % After storage: – after 5 minutes – 0.32 % – after 24 hours was 0.00 %			
	CIPAC MT 171		Determination of dust content: Before storage: 8.3 mg (0.03%) After storage: 11.7 mg (0.04%)			
	CIPAC MT 178.2		Attrition resistance Before storage: 99.76% After storage: 99.76%			
	CIPAC MT 170		The results of size distribution of granules: Before storage:			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			over 3350 µm 0.86% 2000 - 3350 µm 0.52% 1000 - 2000 µm 78.58% 500 - 1000 µm 19.15% 250 - 500 µm 0.09% 125 - 250 µm 0.05% 75 - 125 µm 0.40% Under 75 µm 0.12% After storage: over 3350 µm 0.01% 2000 - 3350 µm 0.02% 1000 - 2000 µm 63.08% 500 - 1000 µm 36.70% 250 - 500 µm 0.09% 125 - 250 µm 0.01% 75 - 125 µm 0.02% Under 75 µm 0.09%			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable. The proposed shelf life is not shorter than 2 years and therefore there is no need to determine shelf life in months (See point KCP 2.7.5).					Not applicable
Wettability (KCP 2.8.1)	CIPAC MT 53.3	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	Wettability of the preparation was equal to 0 s.	Y	BF-109/16 Part IV	Accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	MCPA+Tribenuron metyl 565 SG	1% CIPAC D water solution of the preparation formed 60 ml of foam after 1 min and 39 ml after	Y	BF-109/16 Part I	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	12 min			
	CIPAC MT 47.3	MCPA+Tribenuron metyl 565 SG containing 561 g/kg of MCPA and 13.1 g/kg of tribenuron-methyl Batch no 2/19 Production date: 06.2019	0.25% CIPAC D water solution of the preparation formed 22 ml of foam after 1 min and 7 ml after 12 min 0.5% CIPAC D water solution of the preparation formed 40 ml of foam after 23 min and 39 ml after 12 min		BF- 25/19	
Suspensibility (KCP 2.8.3.1)	Not applicable. MCPA+Tribenuron metyl 565 SG is not water dispersible product.					Not applicable
Spontaneity of dispersion (KCP 2.8.3.2)	Not applicable. MCPA+Tribenuron metyl 565 SG is not water dispersible product.					Not applicable
Dispersion stability (KCP 2.8.3.3)	Not applicable. MCPA+Tribenuron metyl 565 SG is not water dispersible product.					Not applicable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 179.1	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	Residue of tested material – after 5 minutes – 0.75 % – after 18 hours – 0.00 %	Y	BF-109/16 Part I	Accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 170	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	The results of size distribution of granules: over 3350 µm 0.86% between 2000 - 3350 µm 0.52% between 1000 - 2000 µm 78.58% between 500 - 1000 µm 19.15% between 250 - 500 µm 0.09% between 125 - 250 µm 0.05% between 75 - 125 µm 0.40% under 75 µm 0.12%	Y	BF-109/16 Part I	Accepted
Wet sieve test (KCP 2.8.5.1.2)	Not applicable. MCPA+Tribenuron metyl 565 SG is not water dispersible product.					Not applicable
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171.1	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	The average dustiness is equal to 8.3 mg (0.03%)	Y	BF-109/16 Part I	Accepted
Particle size of dust (KCP 2.8.5.2.2)	The result of dust content test shows that avarage dustiness of tested material is < 1 % w/w therefore the particle size of the dust does need to be reported.(plese see KCP 2.8.5.2.1).					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2.	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	The average resistance to attrition is equal to 99.87 %	Y	BF-109/16 Part I	Accepted
Hardness and integrity (KCP 2.8.5.4)	Not applicable. The product is not a tablet.					Not applicable
Emulsifiability (KCP 2.8.6.1)	Not applicable. The product is not a emulsion.					Not applicable
Emulsion stability (KCP 2.8.6.2)	Not applicable. The product is not a emulsion.					Not applicable
Re-emulsifiability (KCP 2.8.6.3)	Not applicable. The product is not a emulsion.					Not applicable
Flowability (KCP 2.8.7.1)	The data are required to granules after storage under pressure.					
Pourability (KCP 2.8.7.2)	Not applicable. The product is not a suspension.					Not applicable
Dustability following accelerated storage (KCP 2.8.7.3)	Plese see KCP 2.7.1					
Physical compatibility of tank mixes (KCP 2.9.1)	Not applicable. MCPA+Tribenuron metyl 565 SG will not be used with other products.					Not applicable
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable. MCPA+Tribenuron metyl 565 SG will not be used with other products.					Not applicable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Adhesion to seeds (KCP 2.10.1)	Not applicable. MCPA+Tribenuron metyl 565 SG is not destined for seed treatment.					Not applicable
Distribution to seed (KCP 2.10.2)	Not applicable. MCPA+Tribenuron metyl 565 SG is not destined for seed treatment.					Not applicable
Other/special studies (KCP 2.11)	CIPAC MT 30.1	MCPA+Tribenuron metyl 565 SG containing 565 g/kg of MCPA and 14.6 g/kg of tribenuron-methyl Batch no 4.5/16 Production date: 11.2016	Water content in tested material is equal to 7.57 %.	Y	BF-109/16 Part I	Accepted

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)

The above information is contained in Part B, Section 7 of this documentation.

4.2 Recommended methods and precautions (KCP 4.2)

Procedures for cleaning application equipment and protective clothing

General statement
All application equipment and contaminated protective clothing should be washed/cleaned with water or a diluted detergent solution and thoroughly rinsed. Care should be taken not to spill the contaminated washings from application equipment into waste water channels. Contaminated cleaning liquids should be disposed of safely according to local regulations.

Application equipment:
Product left over in field spraying equipment which has not been sufficiently cleaned may cause damage during sequential treatment of sensitive crops. As a consequence, cleaning out of field spraying equipment is an essential part of the recommendations for use of plant protection product.
Detailed calculation concerning impact on crops after procedure of tank cleaning according to EPPO guideline PP 1/292(1) is presented in Part B, Section 3 of this documentation and below:

Tank cleaning

As HAKSAR TOP 565 SG is an herbicide for control of weeds, an insufficient tank cleaning can cause negative effects on the next crops. Therefore, an appropriate tank cleaning has to be performed after application of HAKSAR TOP 565 SG.
According to Appendix 4 of EPPO guideline PP 1/292(1), up to 2.6% of the spray solution will remain in the PAE following application (according to ISO 16119).

Assuming a dose of 1kg product/ha in 200 L water/ha and a product containing 550 g/kg of MCPA and 15 g/kg of Tribenuron methyl the following would therefore apply:

Table 3.5.2-4: Calculation of washout according to Appendix 4 of EPPO PP 1/292(1)

Calculations	
Amount of a.i. in 1000 L sprayer (assuming 200 L ha^{-1} water)	1000/200 = 5 5 x 1kg product (application dose in 1 ha) = 5kg product in 1000 L sprayer 1 kg product contains 550 g/kg of MCPA and 15 g/kg of tribrnuron methyl, therefore 5kg product (in the 1000 L sprayer), contains 2750 g of MCPA and 75 g of tribenuron methyl.
Amount left in sprayer after spraying (2.6%)	5kg product x 2.6% = 0.13 kg product (containing 71.5 g MCPA and 1.95 g of tribrnuron methyl)
Situation A (without washing)	
Dose applied (at 200 L/ha) to 2.5 ha (without washing)	0.13 kg product / 2.5 ha = 0.052 kg product/ha (containing 28.6 g MCPA and 0.78g of tribrnuron methyl)
Situation B (one washout - procedure)	
Amount of product left in sprayer after 1st stage of washout procedure (washing tank with 1000 L water and then empty it)	0.13 kg product x 2.6% = 0.003338 kg product/ha
Dose applied (at 200 L/ha)	0.003338 kg product / 2.5 ha = 0.001352 kg product / ha

to 2.5 ha after first washout procedure	
Situation C (two washout - procedure)	
Amount left in sprayer after 2nd stage of washout procedure (washing tank with 1000 L water and then empty it)	0.003338 kg product x 2.6% = 0.00008788 kg product/ha
Dose applied (at 200 L/ha) to 2.5 ha after second washout procedure	0.00008788 kg product / 2.5 ha = 0.00003552 kg product/ha

The studies for non-target plants shows (please refer to respective chapter in section 9 of the dRR) that the most sensitive species is *Ducus Carota* with an ER_{50} value of 0.0093 kg product/ha. Assuming a leftover of 2.6% of the spray solution, which results in 0.052 kg product/ha, the TER value without washing (situation A of the table above) is 0.18 which is below the trigger value of 1 and indicate risk. With the theoretical tank residue rate of 0.001352 kg product/ha after one washing (situation B of the table), a TER value of 6.88 is calculated and is above the trigger value of 1 so indicate no risk.

Therefore, farmers may follow good agricultural practice to conduct cleaning procedures of the spray equipment one time after application, as the TER trigger value of 1 is exceeded after the first cleaning procedure. However, for safety reasons the farmers are on current labels instructed to "fill and flush the contents of the spray tank a minimum of three times".

Procedure:
Empty the spraying equipment completely on the field just spayed. Remove all filters and nozzles, scrub clean and rinse them with clean water. Put 10 % clean water into tank to cover the agitator. Operate a tank flushing system if fitted. Circulate water through the pump and controls for at least one minute. Drain sprayer, collect washings. Repeat procedure once more. Pump last washing water out through boom feed hoses and pipes. Collect washings. Clean off the outside of the sprayer using minimum water volumes. Collect washings. Replace cleaned nozzles and filters. Collect and put all washings back into the tank and spray out on the field headland, or otherwise safely dispose of them. Ensure the sprayer systems are completely drained before storage. Store Plant Protection Equipment in a properly designated store.

Spray equipment should be cleaned according to normal good agricultural practices, which are considered adequate:

1. Any contamination on the outside of the spraying equipment should be removed by washing with clean water.
2. Rinse inside of tank with clean water and flush through booms and hoses using at least one-tenth of the spray tank volume. Repeat this operation at least three times. After the last time drain tank completely.

Normal procedures should be followed for the cleaning of protective clothing and equipment. Any contamination on the outside of protective equipment should be removed by washing with clean water.

Protective clothing:
All contaminated clothing should be washed/cleaned through with a dilute detergent solution and thoroughly rinsed with clean water.

- Impermeable overalls, boots and face shields should be washed clean and dried.
- Permeable overalls should be laundered after use.
- Disposable overalls and gloves should be washed and disposed of as contaminated waste.
- Gloves and boots should be washed clean, if necessary on the insides as well.

Protective clothing should be washed using clean water separately from the normal work clothing. Clean clothing should be stored away from contaminated clothing in a well-ventilated area separate from the chemical storage area. Damaged or heavily contaminated clothing should be discarded.

Protective equipment for the face and eyes such as face shield and goggles should be cleaned by wiping with a suitable detergent and a wet cloth and left to air dry. It may be necessary to clean this equipment during the application to maintain clear vision. This should be done with a wet cloth and clean water. Damaged eye protection should be discarded.

Protective gloves should be rinsed with water before they are removed from the hands. At the end of each day's use, gloves and rubber boots should be washed with clean water and detergent and left to air dry. Clean items should be stored in a well-ventilated area separate from the chemical storage area. Damaged gloves or boots should be discarded.

Effectiveness of the cleaning procedures

1. Empty the spraying equipment completely on the field just sprayed
2. Dismantle suction, pressure line and nozzle filters and clean thoroughly in water
3. Fill spraying equipment to 10% of tank capacity and stir thoroughly (a rotating cleaning nozzle is recommended)
4. Apply rinsing liquid on the field just sprayed
5. Repeat steps 3 and 4 for a 2nd rinsing
6. Inspect filters again and clean them if visible deposits are present

4.1 Emergency measures in the case of an accident (KCP 4.3)

(a) containment of spillages;
In the event of spillage of larger amounts of the mixture, steps should be taken to prevent spreading to the environment
– prevent entering drains, water reservoirs, rivers, groundwater and soil. Notify appropriate emergency services. Warn others of a hazard. Apply similar precautions in case of fire extinguishing water

In the event of large spills, bund the accumulating mixture and pump it into appropriate, sealed and labelled containers and transfer for recovery or disposal in accordance with the provisions of the Waste Act. To remove debris and small amounts of spilled mixture, use sorbent sets, and in their absence, use diatomaceous earth or sand. Collect absorbant containing the mixture in suitable, sealed and labelled waste containers and recover or dispose it in accordance with the regulations applicable in given country.

(b) decontamination of areas, vehicles and buildings;
No special procedures.

(c) disposal of damaged packaging, absorbents and other materials;
Damaged packages return to the producer. Other materials dispose according to obligatory regulations. Disposal of wastes into the soil, sewage system and waters is forbidden.

(d) protection of emergency workers and residents, including bystanders;
Standard protection of emergency workers is recommended. Bystanders are recommended to be kept far away from the area.

(e) first aid measures
Contact with the skin: remove contaminated clothes and footwear immediately. Use water with soap to rinse off the contaminated skin. If any irritation/sensitization occurs, consult a physician.
Contact with the eyes: Protect the non-irritated eye, remove contact lenses. Rinse contaminated eyes thoroughly with water for 10-15 minutes. Avoid strong stream, due to the risk of corneal damage. After rinsing use a sterilized bandage. Seek medical advice, preferably from an ophthalmologist.
Ingestion: call a physician immediately, show them the packaging or label. Do not induce vomiting. Rinse

mouth with water and drink plenty of water. Do not administer anything orally to an unconscious person.
Inhalation: Remove victim to fresh air, keep warm and at rest. In case of any discomfort, seek medical aid.

4.2 Packaging and Compatibility with the Preparation (KCP 4.4)

RMS conclusion:
Based on two-year study in a PE bag it is allowed to extrapolate the results on all presented packaging materials below.

HAKSAR TOP 565 SG will be commercially available in the following packages:

- 1 kg; 5 kg - HDPE or HDPE/LDPE or LDPE heat sealed, machine-molded bags, packed in printed cardboard boxes;

  Polyethylene (HDPE or HDPE/LDPE or LDPE) 0.08 – 0.150 mm ± 30%

- 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

- 1L - PE/PA bottles (polyethylene/polyamide),

- 3L, 5L, 10L, 20L - HDPE or HDPE/LDPE containers/canisters

- 2L, 3L, 5L, 10L – PE/PA (containers/canisters)

Professional user

Specification data for the above indicated packagings:

Type	**1 L bottle**	**3 L canister**	**5 L canister**	**10 L canister**	**20 L canister**
Material:	HDPE or HDPE and LDPE	HDPE or HDPE and LDPE	HDPE or HDPE and LDPE	HDPE or HDPE and LDPE	HDPE or HDPE and LDPE
Shape/size:	Cylindrical Ø 62 or 88.5 ± 5 mm, 240 ± 12.0 mm high	rectangular 201 or 242 ± 15 mm high 161.7 or-192 ± 10 mm length 118.5 or 125 ± 7 mm width	rectangular 320 or 329 ± 16 mm high 186 ± 10 mm length 135 ± 7 mm width	rectangular 376 ± 19 mm high 232 ± 12 mm length 167 ± 9 mm width	rectangular 376 or 386 ± 20 mm high 290 or 297.7 ± 15 mm length 248 or 264 ± 14 mm width
Opening:	Ø 40 ± 4.0 mm	Ø 36 or 42 ± 4.0 mm	Ø 54 or 57.3 ± 6 mm	Ø 40 or 54 or 59 ± 6 mm	Ø 48.5 or 51.4 ± 6 mm
Closure:	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type with an element breakable when opening
Seal:	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/EPE 250/PE
Manner of construction	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding

UN/ADR	Compliant with the current UN and ADR requirements for packaging testing.

Type	**1 L bottle**	**2 L canister**	**3 L canister**	**5 L canister**	**10 L canister**
Material:	HDPE/PA type Coex	HDPE/PA type Coex	HDPE/PA type Coex	HDPE/PA type Coex	HDPE/PA type Coex
Shape / size	cylindrical / Ø 84 mm or 88,5 ± 5 mm, 239 or 248.2 ± 12 mm high	rectangular, 255 ± 12 mm high 140 ± 8 mm length, 94 ± 6 mm width	rectangular, 241 ± 12 mm high, 193 ± 10 mm length, 142 ± 8 mm width	rectangular, 335 ± 20 mm high, 186 ± 10 mm length, 135 or 140 ± 8 mm width	rectangular, 376.0 ± 19 mm high, 232 or 240 ± 12 mm length, 167 or 180 ± 9 mm width
Opening	Ø 39.7 or 42 mm ± 4 mm	Ø 42 mm ± 4 mm	Ø 54 ± 6 mm	Ø 53 or 57.3 mm ± 6 mm	Ø 54 or 57.3 ± 6 mm
Closure	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process
Seal:	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE
Manner of construction	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding

UN/ADR	Compliant with the current UN and ADR requirements for packaging testing.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.4.2 KCP 2.6.2 KCP 2.8.2 KCP 2.8.4 KCP 2.8.5.1.1 KCP 2.8.5.2.1 KCP 2.8.5.2.2 KCP 2.8.5.3 KCP 2.11	Al Amin Idris	2017	MCPA + TRIBENURON METYL 565SG Part I: Determination of physicalchemical properties of the initial preparation IPO Warszawa, Poland BF-109/16 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.2.1	Buczkowski Daniel	2017	MCPA + TRIBENURON METYL 565SG – Determination of explosives properties IPO Warszawa, Poland BW-41/16 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.2.2 KCP 2.3.2 KCP 2.3.3	Flasińska Paulina	2017	MCPA + TRIBENURON METYL 565SG – Determination of flammability, relative self-ignition temperature and oxidising properties for solids. Company: IPO Warszawa, Poland BC-27/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.7.2	Averalo Enzo	2019	MCPA + TRIBENURON METYL 565SG – Determination of pchysicochemical properties of the initial preparation of the accelarated storage Company: IPO Warszawa, Poland BF-25/19 GLP	N	CIECH Sarzyna S.A.

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			Unpublished		
KCP 2.7.2	Averalo Enzo	2021	MCPA + TRIBENURON METHYL Evaluation of physicochemical properties IPO Warszawa, Poland BF- 11/21 GLP Unpublished	N	CIECH Sarzyna S.A
KCP 2.7.5 KCP 2.8.1	Averalo Enzo	2019	MCPA + TRIBENURON METYL 565SG. Part IV. Determination of physicochemical properties after second year of storage. IPO Warszawa, Poland BF-109/16 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.8.2	Averalo Enzo	2019	MCPA + TRIBENURON METYL 565 SG Determination of physicochemical properties Company: IPO Warszawa, Poland BF- 25/19 GLP Unpublished	N	CIECH Sarzyna S.A.

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 MCPA

No new data on physical and chemical properties of the active substance were submitted.

A 2.2 Tribenuron-methyl

No new data on physical and chemical properties of the active substance were submitted.