

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: T-75WG-OR2-C

Product name(s): TOSCANA TOP 75 WG

Chemical active substance(s):

Tribenuron-methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2020

MS Finalisation date: 15/10/2021

Version history

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

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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).

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

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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 Tribenuron-methyl

Tribenuron-methyl min. 975 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: TOSCANA TOP 75 WG
Company code number: T-75WG-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)
Tribenuron-methyl	750 g/kg	725 - 775 g/kg	769 g/kg	76.9 %

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

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 active substance

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)

CONFIDENTIAL information is provided separately (Part C).

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

Type: Water dispersible granules

[Code: WG]

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

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 T-75WG-OR2-C 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	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	Cylindrical bright beige granules of light characteristic odour	Y	BF-110/16 Part I	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	The tested material does not have explosive properties according to the criteria of EEC A.14 method.	Y	BW-40/16	Accepted
Oxidizing properties (KCP 2.2.2)	EEC A.17	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	The tested material has no oxidizing properties according to A.17 method.	Y	BC-26/17	Accepted
Flash point (KCP 2.3.1)	Not applicable. Tribenuron metyl 75 WG is a solid formulation. Determination of flash point is applicable only for liquid substances whose vapours can be ignited by ignition sources.					Not applicable
Flammability (KCP 2.3.2)	EEC A. 10	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	The tested material is not highly flammable in accordance with test A.10. criteria.	Y	BC-26/17	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Self-heating (KCP 2.3.3)	EEC A.16	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	The tested material does not have the relative self-ignition temperature in accordance with test A.16. criteria.	Y	BC-26/17	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	Not applicable. Tribenuron metylu 75 WG is a solid.					
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	pH = 6.01 at 20 °C (pH of 1% water solution).	Y	BF-110/16 Part I	Accepted
Viscosity (KCP 2.5.1)	Not applicable. Tribenuron metylu 75 WG is a solid.					Not applicable
Surface tension (KCP 2.5.2)	Not applicable. Tribenuron metylu 75 WG is a solid.					Not applicable
Relative density (KCP 2.6.1)	Not applicable. Tribenuron metylu 75 WG is a solid.					Not applicable
Bulk density (KCP 2.6.2)	CIPAC MT 186	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	The average measured pour density was pour 0.57 g/ml and tap 0.63 g/ml	Y	BF-110/16 Part I	Accepted
Storage Stability after 14 days at 54° C	According to FAO specification for Tribenuron-methyl this substance could be sensitive to higher temperatures therefore the accelerated storage test was carried out at 35 °C for 12 weeks (please see point KCP 2.7.2).					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.1)						
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 170	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	<p>After storage at (35±2) °C for 12 weeks in glass beaker the product was still cylindrical bright brown granules with characteristic odour</p> <p>Detailed results after accelerated storage stability procedure are presented below:</p> <p>The content of the active substance: Before storage: 73.92% (739.2 g/kg) After storage: 75.38% (753.8 g/kg)</p> <p>pH value of 1% dispersion: Before storage: 6.01 After storage: 5.97</p> <p>Dry sieve test: Before storage: over 3350 µm 0.02% 2000 – 3350 µm 0.33% 1000 – 2000 µm 75.68% 500 – 1000 µm 21.35% 250 – 500 µm 0.59% 125 – 250 µm 0.51% 75 – 125 µm 0.63% Under 75 µm 0.91%</p> <p>After storage: over 3350 µm 0.05% 2000 – 3350 µm 0.35% 1000 – 2000 µm 60.80% 500 – 1000 µm 37.78%</p>	Y	BF-110/16 Part II	<p>Accepted</p> <p>The sample was stored in glass beaker. All tested parameter are accepted</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>250 – 500 µm 0.35% 125 – 250 µm 0.33% 75 – 125 µm 0.16% Under 75 µm 0.20%</p> <p>The suspensability of 1% dispersion: Before storage: 99.77% After storage: 99.27%</p> <p>The spontaneity of dispersion: Before storage: 80.77% After storage: 82.88%</p> <p>The content of dust: Before storage: 1.20 mg (0.00%) After storage: 0.6 mg (0.00%)</p> <p>Attrition resistance: Before storage: 99.74% After storage: 99.79%</p> <p>Wet sieve test: Before storage: 1.10% After storage: 0.95%</p> <p>Determination of particle size distribution: Before storage: d₁₀ = 0.57 µm d₅₀ = 1.61 µm d₉₀ = 4.12 µm d_{4,3} = 2.01 µm SD = 0.015 µm, RSD = 0.746%</p>			
	CIPAC MT 184					
	CIPAC MT 174					
	CIPAC MT 171.1					
	CIPAC MT 178.2					
	CIPAC MT 185					
	CIPAC MT 187					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 172.1		<p>After storage: $d_{10} = 0.55 \mu\text{m}$ $d_{50} = 1.63 \mu\text{m}$ $d_{90} = 4.27 \mu\text{m}$ $d_{4,3} = 2.05 \mu\text{m}$ $SD = 0.013 \mu\text{m}$, $RSD = 0.634\%$</p> <p>Flowability was 100% after accelerated storage</p>			
cd. Stability after storage for other periods and/or temperatures (KCP 2.7.2)	<p>CIPAC MT 184</p> <p>CIPAC MT 53.3</p>	<p>Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016</p>	<p>Detailed results after accelerated storage stability procedure are presented below:</p> <p>The suspensability of 0.005% dispersion: Before storage: 91.47% After storage: 92.41%</p> <p>The suspensability of 0.025% dispersion: Before storage: 92.26% After storage: 90.15%</p> <p>Wettability was 0 s after accelerated storage</p>	Y	BF-110/16 Part II Annex no. 1	Accepted
Minimum content after heat stability testing (KCP 2.7.3)	CIPAC MT 46.3	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl	<p>The content of the active substance: Before storage: 73.92% (739.2 g/kg) After storage: 75.38% (753.8 g/kg)</p>	Y	BF-110/16 Part II	Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch no 12/16 Production date: 10.2016	The active substance content has not decreased by more than 5% of the initial content after the heat stability test (see point IIIA 2.7.2).			
Effect of low temperatures on stability (KCP 2.7.4)	Not applicable. Tribenuron metylu 75 WG is a solid.					Not applicable
Ambient temperature shelf life (KCP 2.7.5)	GIFAP Technical Monograph No. 17 and Visual inspection CIPAC MT 75.3 CIPAC MT 170 CIPAC MT 53.3 CIPAC MT 184 CIPAC MT 187 CIPAC MT 185 CIPAC MT 171.1 CIPAC MT 178.2 CIPAC MT 174 HPLC UV Vis CIPAC MT 176 (soluble bags) CIPAC MT 47.3 (soluble bags)	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	No changes in the tribenuron methyl active ingredient content and in the physico-chemical properties (pH value, wettability, wet sieve test, dustiness, attrition resistance, particle size distribution, suspensibility and dispersibility) were found in the formulation sample stored in a PE bags, HDPE bottles and soluble bags in Metlam foil for 24 months of storage at ambient temperature compared with the results obtained before storage. From the above reported data, it can be concluded that the Tribenuron metyl 75 WG formulation sample is stable in its commercial packaging during 24 months storage. For details please see table below.	Y	BF-110/16 Part IV and Part V BF-29/19	Accepted The PPP was stored in in a PE bags, HDPE bottles and soluble bags in Metlam foil. These packs remained intact after storage. For full details on physicochemical parameters refer to the table below Summarizing, a shelf life of two year can be granted for this PPP.
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.	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-	Wettability of the preparation was equal to 0 s.	Y	BF-110/16 Part I	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		methyl Batch no 12/16 Production date: 10.2016				
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron- methyl Batch no 12/16 Production date: 10.2016	1% CIPAC D water dispersion of the preparation formed 4 ml of foam after 1 min and 0 ml after 12 min 0.005% CIPAC D water dispersion of the preparation formed 2 ml of foam after 1 min and 0 ml after 12 min 0.025% CIPAC D water dispersion of the preparation formed 9 ml of foam after 1 min and 2 ml after 12 min	Y	BF-110/16 Part IV	Accepted
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron- methyl Batch no 12/16 Production date: 10.2016	Stability of 1% water dispersion of the preparation in CIPAC D water is equal to 99.77%. Stability of 0.005% ater dispersion of the preparation in CIPAC D water is equal to 91.47%. Stability of 0.025% ater dispersion of the preparation in CIPAC D water is equal to 92.26%.	Y	BF-110/16 Part V	Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron- methyl Batch no 12/16 Production date: 10.2016	Stability of dispersion is equal to 80.77%	Y	BF-110/16 Part I	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dispersion stability (KCP 2.8.3.3)	Not applicable for WG formulations.					Not applicable
Degree of dissolution and dilution stability (KCP 2.8.4)	Not applicable for WG formulations.					Not applicable
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 170	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	over 3350 µm 0.02% between 2000 - 3350 µm 0.33% between 1000 - 2000 µm 75.68% between 500 - 1000 µm 21.35% between 250 - 500 µm 0.59% between 125 - 250 µm 0.51% between 75 - 125 µm 0.63% under 75 µm 0.91%	Y	BF-110/16 Part I	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	Residue in 75 µm sieve 1.10%	Y	BF-110/16 Part I	Accepted
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171.1	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	Content of dust was equal to 1.20 mg (0.00%)	Y	BF-110/16 Part I	Accepted
Particle size of dust (KCP 2.8.5.2.2)	CIPAC MT 187	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16	Particle size of dust was as follows: d ₁₀ = 0.57 µm d ₅₀ = 1.61 µm d ₉₀ = 4.12 µm	Y	BF-110/16 Part I	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Production date: 10.2016	d _{4,3} = 2.01 µm SD = 0.015 µm, RSD = 0.746 %			
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	Attrition resistance of tested material was equal to 99.74%	Y	BF-110/16 Part I	Accepted
FdustHardness 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)	CIPAC MT 172.1	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	100% after accelerated storage	Y	BF-110/16 Part II	Accepted
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)	CIPAC MT 171.1	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl	The average dustiness after accelerated storage is equal to 0.6 mg (0.00%)	Y	BF-110/16 Part II	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch no 12/16 Production date: 10.2016				
Physical compatibility of tank mixes (KCP 2.9.1)	Not applicable. Tribenuron metyl 750 WG will not be used with other products.					Not applicable
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable. Tribenuron metyl 750 WG will not be used with other products.					Not applicable
Adhesion to seeds (KCP 2.10.1)	Not applicable. Tribenuron metyl 750 WG is not destined for seed treatment.					Not applicable
Distribution to seed (KCP 2.10.2)	Not applicable. Tribenuron metyl 750 WG is not destined for seed treatment.					Not applicable
Other/special studies (KCP 2.11)	CIPAC MT 30.1	Tribenuron metylu 75 WG containing 738.3 g/kg of tribenuron-methyl Batch no 12/16 Production date: 10.2016	Water content in tested material is equal to 1.51%	Y	BF-110/16 Part I	Accepted

Results after 24 months storage at ambient temperature:

Test	Initial results	After storage PE bags	After storage HDPE bottles	After storage Water soluble sacks packed in silvery Metlam bags
Tribenuron methyl a.i. content	73.92% (739.2 g/kg)	73.50% (735.0 g/kg)	74.31% (743.1 g/kg)	74.01% (740.1 g/kg)

Appearance (Colour, odour and physical state)	Cylindrical bright beige granules of light characteristic odour	Cylindrical beige granules of light characteristic odour	Cylindrical beige granules of light characteristic odour	Cylindrical beige granules of light characteristic odour
Visual examination of packaging		The shape and colour of the packaging were stable. The minor mass change of the packages has no effect on the physicochemical properties of the tested preparation.	The shape and colour of the packaging were stable. The minor mass change of the packages has no effect on the physicochemical properties of the tested preparation.	The shape and colour of the packaging were stable. The minor mass change of the packages has no effect on the physicochemical properties of the tested preparation.
pH value (1% dispersion)	6.01	6.05	6.07	5.57
Wettability	0 s	0 s	0 s	1 s
Wet sieve	Residue in 75 µm sieve 1.10%	Residue in 75 µm sieve 0.85%	Residue in 75 µm sieve 0.90%	Residue in 75 µm sieve 1.1%
Dustiness	1.20 mg (0.00%)	“nearly dust-free” 0.70 mg (0.00%)	“nearly dust-free” 0.60 mg (0.00%)	“nearly dust-free” 0.6 mg (0.00%)
Particle size distribution	over 3350 µm 0.02% 2000 – 3350 µm 0.33% 1000 – 2000 µm 75.68% 500 – 1000 µm 21.35% 250 – 500 µm 0.59% 125 – 250 µm 0.51% 75 – 125 µm 0.63% Under 75 µm 0.91%	over 3350 µm 0.00% between 2000 - 3350 µm 0.01% between 1000 - 2000 µm 65.32% between 500 - 1000 µm 33.10% between 250 - 500 µm 0.72% between 125 - 250 µm 0.42% between 75 - 125 µm 0.19% under 75 µm 0.25%	over 3350 µm 0.01% between 2000 - 3350 µm 0.01% between 1000 - 2000 µm 66.67% between 500 - 1000 µm 31.05% between 250 - 500 µm 1.33% between 125 - 250 µm 0.41% between 75 - 125 µm 0.25% under 75 µm 0.31%	over 3350 µm 0.20% between 2000 - 3350 µm 0.01% between 1000 - 2000 µm 64.29% between 500 - 1000 µm 33.22% between 250 - 500 µm 1.07% between 125 - 250 µm 0.66% between 75 - 125 µm 0.25% under 75 µm 0.32%
Attrition resistance of dispersible granules		99.87%	99.77%	99.87%
Suspensibility	0.005 % - 91.47% 0.025 % - 92.26% 1 % - 99.77%	0.005 % - 103.44% 0.025 % - 100.84% 1 % - 92.53%	0.005 % - 96.17% 0.025 % - 98.68% 1 % - 93.60%	0.005 % - 89.63% 0.025 % - 95.95% 1 % - 92.70%
Dispersibility	80.77%	81.55%	81.61%	82.88%

Persistent foam		Not applicable	Not applicable	0.005 % - 3 ml after 1 min, 0 ml after 12 min 0.025 % - 5 ml after 1 min, 0 ml after 12 min 1 % - 0 ml after 1 min, 0 ml after 12 min
Dissolution rate for soluble bags	Filtration duration 6 s, clean sieve	Not applicable	Not applicable	Filtration duration 9 s, clean sieve

RMS conclusion

These data allow to accept the two-year shelf life for this PPP.

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:

As TOSCANA TOP 75 WG 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 TOSCANA TOP 75 WG.

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 0.025kg product/ha in 200 L water/ha and a product containing 750 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)	$1000/200 = 5$ $5 \times 1\text{ kg product (application dose in 1 ha)} = 5\text{ kg product in 1000 L sprayer}$ $25/200 = 0.125$ 0.025 kg product contains 18.75 g/kg of tribenuron methyl, therefore 0.125kg product (in the 1000 L sprayer), 93.75 g of tribenuron methyl.
Amount left in sprayer after spraying (2.6%)	$0.125\text{ kg product} \times 2.6\% = 0.13\text{ kg product (containing 97.5 g of tribenuron methyl)}$
Situation A (without washing)	
Dose applied (at 200 L/ha) to 2.5 ha (without washing)	$0.13\text{ kg product} / 2.5\text{ ha} = 0.00325\text{ kg product/ha (2.43g of tribenuron methyl)}$

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)	$0.13 \text{ kg product} \times 2.6\% = 0.00325 \text{ kg product/ha}$
Dose applied (at 200 L/ha) to 2.5 ha after first washout procedure	$0.00325 \text{ kg product} / 2.5 \text{ ha} = 0.0013 \text{ kg product / ha}$
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)	$0.00325 \text{ kg product} \times 2.6\% = 0.0000845 \text{ kg product/ha}$
Dose applied (at 200 L/ha) to 2.5 ha after second washout procedure	$0.0000845 \text{ kg product} / 2.5 \text{ ha} = 0.0000338 \text{ kg product/ha}$

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 1.6 kg product/ha. Assuming a leftover of 2.6% of the spray solution, which results in 0.00325 kg product/ha, the TER value without washing (situation A of the table above) is 429 which is above the trigger value of 1 and no indicate 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 even without washing 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 sprayed. 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 absorbent 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: immediately remove contaminated clothing and shoes. Thoroughly wash the exposed parts of the skin with soapy water. If signs of irritation / sensitisation occur, consult a doctor.

Contact with the eyes: If in eyes: Protect non-affected eye, remove contact lenses. Thoroughly wash contaminated eyes with water for 10-15 minutes. Avoid strong water jet as this poses risk of mechanical damage to cornea. After washing wear sterile eye patch. Seek medical advice, preferably an ophthalmologist

Ingestion: call for medical assistance immediately and show the container or label. Do not induce vomiting. Thoroughly wash the mouth with water and drink plenty of water afterwards. Never give anything orally to an unconscious person.

Inhalation: move the injured person to fresh air, provide warmth and rest. If any worrying symptoms develop seek medical attention.

4.2 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.2-1: Packaging information

RMS conclusion:

Based on the two-year storage stability study all following packs are acceptable for this WG formulation

The product is contained in packs of 8 g capacity up to 500 g in the:

1/ the bags (PE) packed in printed cardboard boxes

Package Size:	10 g	20 g	50 g	100 g	250 g
Material:	Polyethylene 0.08 – 0.150 mm ± 30% (HDPE or HDPE/LDPE or LDPE)				
Closure:	Thermosealed				

2/ the bags Metlam (PET/Alu/LDPE or PP/Alu/LDPE) with print or packed in printed cardboard boxes

Package Size:	10 g	20 g	50 g	100 g	250 g
Material:	Polyester 12 µm ± 30% + Aluminium 7 µm ± 30% + Polyethylene 75 µm ± 30% (PET/Alu/PE or PP/Alu/PE)				
Closure:	Thermosealed				

3/ the water-soluble bags (PVAL) in the bags METLAM (PP/AL/PE or PET/Alu/PE) E

Package Size:	10 g	20 g	50 g	100 g
Material:	polyvinyl alcohol 25 - 150 µm ± 30% (PVAL)			
Closure:	Thermosealed bags			

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 2.8.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.5.2.2 KCP 2.8.5.3 KCP 2.11	Xxxxxx	2017	Tribenuron metylu 75 WG Part I: Determination of physicochemical properties of the initial preparation BF - 110/16 Institute of Industrial Organic Chemistry GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 2.2.1	Xxxxxx	2017	Tribenuron metylu 75 WG Determination of explosives properties BW - 40/16 Institute of Industrial Organic Chemistry GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 2.2.2 KCP 2.3.2 KCP 2.3.3	Xxxxxx	2017	Tribenuron metylu 75 WG Determination of flammability, relative self ignition temperture and oxidising properties BC - 26/17 Institute of Industrial Organic Chemistry GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 2.7.2 KCP 2.7.3 KCP 2.8.7.1 KCP 2.8.7.3	Xxxxxx	2017	Tribenuron metylu 75 WG Part II: Determination of physicochemical properties after accelerated storage BF - 110/16 Institute of Industrial Organic Chemistry GLP	N	CIECH Sarżyna 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	Xxxxxx	2017	Tribenuron metylu 75 WG Part II: Determination of physicochemical properties after accelerated storage Annex No. 1 to BF - 110/16 Institute of Industrial Organic Chemistry GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 2.7.5 KCP 2.8.2	Xxxxxx	2019	Tribenuron metyl 75 WG Part IV: Determination of physicochemical properties after two years storage in water soluble bags BF - 110/16 ŁUKASIEWICZ Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 2.7.5 KCP 2.8.3.1	Xxxxxx	2019	Tribenuron metyl 75 WG Part V: Determination of physicochemical properties after two years storage PE and HDPE packages BF - 110/16 ŁUKASIEWICZ Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	CIECH Sarżyna S.A.
KCP 2.7.5	Xxxxxx	2019	Tribenuron metyl 75 WG Determination of physicochemical properties after the second year of storage in water soluble bags BF - 29/19 ŁUKASIEWICZ Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	CIECH Sarżyna S.A.

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

Tribenuron-methyl

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