

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: TOTO 75 SG

Product name(s): TOTO 75 SG, TYTAN 75 SG, HERKULES 75 SG

Chemical active substance(s):

Thifensulfuron-methyl, 682 g/kg

Metsulfuron-methyl, 68 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: June 2021

MS Finalisation date: July 2021, October 2022

TOTO 75 SG/ TOTO 75 SG, TYTAN 75 SG, HERKULES 75 SG

Part B – Section 1, 2 and 4 - Core Assessment

Applicant version

Version history

When	What
July 2021	Finalisation of the assessment by zRMS
October 2022	Final Registration Report

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<u>Appendix 1</u>	Błąd! Nie zdefiniowano zakładki.
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zRMS comment: Data presented below are sufficient for evaluation. Studies submitted during renewal of authorization have been evaluated and accepted. Tank mix compatibility with GALAPER 200 EC, Asystem+ and with Partner+ was confirmed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE), which is compatible with the formulation and is deemed to be acceptable.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Innvigo Sp. z o.o.
 Address: Innvigo Sp. z o.o.
 Aleje Jerozolimskie 178
 02-486 Warsaw, Poland

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 Thifensulfuron-methyl

According to ~~SANTE/10150/2016 rev.2 12 July 2016~~

Thifensulfuron-methyl	min. 960 g/kg (SANTE/10150/2016 rev.2 12 July 2016)
	min 975 g/kg (Innvigo's source)

1.2.3.2 Metsulfuron-methyl

According to the ~~SANTE/10319/2015 Rev. 3 11 December 2015~~

Metsulfuron methyl	min. 967 g/kg (SANTE/10319/2015 Rev. 3 11 December 2015 and EFSA J. 2015;13(1):3936)
	min 975 g/kg (Innvigo's source)

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

Trade name: Please refer to Registration Report Part A for the relevant country (or)
 Trade name: TOTO 75 SG
 TYTAN 75 SG
 HERKLUES 75 SG
 Company code number: TOTO 75 SG

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 1.41: 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)
Metsulfuron-methyl	68	61.2 – 74.8	69.4
Thifensulfuron-methyl	682	657 – 707	695.9 699.5

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

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

Table 1.42: Information on thifensulfuron-methyl

Type	Name/Code Number
ISO common name	Thifensulfuron-methyl
CAS No.	79277-27-3
EC No.	616-673-4
CIPAC No.	452

Table 1.43: Information on Metsulfuron-methyl

Type	Name/Code Number	
ISO common name	Metsulfuron methyl	N/A
CAS No.	74223-64-6	
EC No.	Not allocated	
CIPAC No.	441.201	

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 soluble granules

[Code: SG]

1.6 Function (KCP 1.6)

Herbicide in the form of water soluble granules

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 whitish, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 6.5 at 20 °C. There is no effect of ~~low and~~ high temperature on the stability of the formulation, since after ~~7 days at 0 °C and~~ 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed significantly. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE*. Its technical characteristics are acceptable for a *SG* formulation.

The intended concentration of use is 0.023% to 0.045%.

The product can be mixed in the tank together with GALAPER 200 EC, Asystent+ and with Partner+. Studies regarding the combination with GALAPER 200 EC, Asystent+ and with Partner+ were submitted and the application as tank mixture is acceptable.

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

No Classification is necessary

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not required

Compliance with FAO specifications:

The product TOTO 75 SG complies with FAO specifications.

Formulation used for tests

TOTO 75 SG
Batch No.: 1905/15
Prod.date: 05.2015

TOTO 75 SG
Batch No.: 0109/19-Z
Prod. Date: 10/2019
Expiry date: 10.2021

TOTO 75 SG
Batch No.: TOTO/13.08.2010
Prod. Date: 13.08.2010

TOTO 75 SG
Batch No.: 03.02.2011

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)	Organoleptic	TOTO 75 SG Batch No.: 03.02.2011	Initial 2010: Whitish, cylindrical granules of characteristic odour Initial 2011: Cylindrical granules of greyish colour and characteristic odour	Y	Al Amin, Study code: BF-12/10 Al Amin, Study code: BF 04/11, 2011 Al Amin, Study code: BF 04/11, 2012 Al Amin, Study code: BF 04/11, 2013	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
		TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	After the first year of storage: Greyish cylindrical granular preparation of characteristic odour After the second year of storage: Greyish cylindrical granular preparation of characteristic odour	Y	Al Amin, Study code: BF-04/11, 2011 Al Amin, Study code: BF-04/11, 2012 Al Amin,	
		TOTO 75 SG Batch: 03.02.2011	Initial 2011: Cylindrical granules of greyish colour and characteristic odour After 9 months of storage: Cylindrical granules of greyish colour and characteristic odour After the first year of storage: Greyish cylindrical granular preparation of characteristic odour After the second year of storage: Greyish cylindrical granular preparation of characteristic odour			Accepted

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					Study code: BF-04/11, 2013	
Explosive properties (KCP 2.2.1)	EEC A14	TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	Not explosive according to the criteria of EEC A.14 method.	Y	T. Sałaciński, Study code: BW-08/10	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
Oxidizing properties (KCP 2.2.2)	EEC A17	TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	No oxidising properties according to EEC method A 17.	Y	M. Frączak, Study code: BC-27/10	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
Flash point (KCP 2.3.1)	EEAC A14	TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	No self-ignition up to 400 °C	Y	M. Frączak, Study code: BC-27/10	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
Flammability	EEC A10	TOTO 75 SG	Not highly flammable according to EEC method A 10.	Y	M. Frączak,	Previously

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.3.2)		Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010			Study code: BC-27/10	accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
Self-heating (KCP 2.3.3)	EEC A14	TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	No self-ignition up to 400 °C	Y	M. Frączak, Study code: BC-27/10	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
Acidity or alkalinity and pH (KCP 2.4.1)			NR			Not required
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	Procedure no. SPR/BF/02/b and CIPAC MT 75	TOTO 75 SG Batch No.: 03.02.2011 TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	Initial 2010: pH=6.43 in 1% water solution After 14 d at 54°C pH=6.28 in 1% water solution Initial 2011: pH=6.53 After the first year of storage pH= 5.6 After the second year of storage:	Y	Al Amin, Study code: BF-12/10 Al Amin, Study code: BF-04/11, 2011 Al Amin, Study code:	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			pH=6.65		BF-04/11, 2012 Al Amin, Study code: BF-04/11	
		TOTO 75 SG Batch: 03.02.2011	Initial 2011: pH=6.53 After 9 months of storage: pH= 6.43 After the first year of storage pH= 5.6 After the second year of storage: pH=6.65	Y	Al Amin, Study code: BF-04/11, 2011 Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	Accepted
Viscosity (KCP 2.5.1)			NR			Not required
Surface tension (KCP 2.5.2)			NR			Not required
Relative density (KCP 2.6.1)			NR			Not required
Bulk density (KCP 2.6.2)	Procedure no. SPR/BF-C/17/b. and CIPAC MT	TOTO 75 SG Batch No.: TOTO/13.08.2010	Tap density = 0.61 g/ml	Y	Al Amin, Study code: BF-12/10	Previously accepted (primary authorization)

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments														
	169					No 104/2012 from 09.08.2012, with further changes)														
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46 HPLC-DAD Procedure no. SPR/BF-C/18/b and CIPAC Method MT 59.1	TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	Content a.s. after 14 days at 54° C [Met]=66.8 g/kg RSD=1.24% [Thifen]= 713.4 g/kg RSD=0.84% Particle size after 14 d @54° C (dry sieve test) : <table border="1" data-bbox="750 874 1075 1177"> <thead> <tr> <th>Fraction</th> <th>[%]</th> </tr> </thead> <tbody> <tr> <td>>1400 µm</td> <td>0.13</td> </tr> <tr> <td>1000 - 1400 µm</td> <td>92.73</td> </tr> <tr> <td>710 - 1000 µm</td> <td>6.74</td> </tr> <tr> <td>500 - 710 µm</td> <td>0.18</td> </tr> <tr> <td>300 - 500 µm</td> <td>0.13</td> </tr> <tr> <td><300 µm</td> <td>0.09</td> </tr> </tbody> </table> Wet sieve test, wettability, flowability, dust content remained unchanged	Fraction	[%]	>1400 µm	0.13	1000 - 1400 µm	92.73	710 - 1000 µm	6.74	500 - 710 µm	0.18	300 - 500 µm	0.13	<300 µm	0.09	Y	Al Amin, Study code: BF-12/10	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Organoleptic CIPAC MT 75 HPLC	TOTO 75 SG Batch No.: 03.02.2011	<table border="1"> <thead> <tr> <th rowspan="2">Test</th> <th rowspan="2">Guideline and method</th> <th colspan="2">Findings</th> </tr> <tr> <th>Initial material</th> <th>After nine months of storage</th> </tr> </thead> <tbody> <tr> <td>Physical state colour and odour</td> <td>Visual inspection, nasal inhalation</td> <td>Cylindrical granules of greyish colour and characteristic odour</td> <td>Cylindrical granules of greyish colour and characteristic odour</td> </tr> <tr> <td>pH of water solution</td> <td>CIPAC MT 75</td> <td>6.53 units</td> <td>6.46 units</td> </tr> <tr> <td rowspan="2">Content of active ingredients</td> <td rowspan="2">HPLC</td> <td>metsulfuron-methyl 6.62 % (66.2 g/kg)</td> <td>metsulfuron-methyl 6.64 % (66.4 g/kg)</td> </tr> <tr> <td>thifensulfuron methyl 68.14 % (681.4 g/kg)</td> <td>tribenuron-methyl 68.22 % (682.2 g/kg)</td> </tr> </tbody> </table>	Test	Guideline and method	Findings		Initial material	After nine months of storage	Physical state colour and odour	Visual inspection, nasal inhalation	Cylindrical granules of greyish colour and characteristic odour	Cylindrical granules of greyish colour and characteristic odour	pH of water solution	CIPAC MT 75	6.53 units	6.46 units	Content of active ingredients	HPLC	metsulfuron-methyl 6.62 % (66.2 g/kg)	metsulfuron-methyl 6.64 % (66.4 g/kg)	thifensulfuron methyl 68.14 % (681.4 g/kg)	tribenuron-methyl 68.22 % (682.2 g/kg)	Y	Al Amn, Study code: BF-04/11, 2011	Appearance, pH and the content of active ingredients after storage – acceptable. No results of wettability, dilution stability, wet sieve, dry sieve, dust content, attrition tests and no information regarding packaging stability after storage. Not accepted
Test	Guideline and method	Findings																								
		Initial material	After nine months of storage																							
Physical state colour and odour	Visual inspection, nasal inhalation	Cylindrical granules of greyish colour and characteristic odour	Cylindrical granules of greyish colour and characteristic odour																							
pH of water solution	CIPAC MT 75	6.53 units	6.46 units																							
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Minimum content after heat stability testing (KCP 2.7.3)	CIPAC MT 46	TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	Content a.s. after 14 days at 54° C [Met]=66.8 g/kg RSD=1.24% [Thifen]= 713.4 71.34 RSD=0.84%	Y	Al Amin, Study code: BF-12/10	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)																				

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Effect of low temperatures on stability (KCP 2.7.4)			NR			Not required
Ambient temperature shelf life (KCP 2.7.5)	<p>Technical Monograph GIFAP No 17</p> <p>Organoleptic</p> <p>HPLC</p> <p>CIPAC MT 75</p> <p>CIPAC MT 53</p> <p>CIPAC MT 179</p> <p>CIPAC MT 59.1</p> <p>CIPAC MT 182</p> <p>CIPAC MT 171</p>	TOTO 75 SG Batch No.: 03.02.2011	<p><u>Colour, odour and physical state</u> Method: Visual inspection Initial 2010: Whitish, cylindrical granules of characteristic odour Initial 2011: Cylindrical granules of greyish colour and characteristic odour After one year: Greyish cylindrical granular preparation of characteristic odour After 2 years of storage: Greyish cylindrical granular preparation of characteristic odour</p> <p><u>A.s. content:</u> Method: HPLC Initial 2010: Metsulfuron: 6.73% Thifensulfuron: 70.84%</p> <p>Initial 2011: Metsulfuron: 6.62% Thifensulfuron: 68.14%</p> <p>After one year: Metsulfuron: 6.51% Thifensulfuron: 67.61%</p> <p>After 2 years of storage: Metsulfuron: 6.27% Thifensulfuron: 67.96%</p> <p><u>pH of 1% water solution</u> Method: CIPAC MT 75 Initial 2010: pH = 6.43 Initial 2011: pH=6.53 After one year: pH = 5.60 After 2 years of storage: pH = 6.65</p>	Y	<p>Al Amin, Study code: BF-12/10</p> <p>Al Amin, Study code: BF-04/11, 2011</p> <p>Al Amin, Study code: BF-04/11, 2012</p> <p>Al Amin, Study code: BF-04/11, 2013</p>	<p>The results of the physicochemical properties and a.s. contents after 1 year of storage are acceptable. The shape and colour of the HDPE packages were stable after storage. The minor mass change of the packages reported. Data gap – attrition was not determined</p> <p>Evaluation of 2 years storage from zRMS PL, Dec. 2016: <i>The change in a.s. content</i></p>

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			<p><u>Wettability</u> Method: CIPAC MT 53.3 Initial: spontaneous After one year: 0.00 s After 2 years of storage: 0.00 s</p> <p><u>Dilution stability</u> Method: CIPAC MT 179 Initial: no residue in a 75 µm sieve after 5 minutes and 18 hours after dissolving: - after 5 minutes of dissolving 0.33% - after 18 hours of dissolving 0.00% After one year: - after 5 minutes of dissolving 0.34% - after 18 hours of dissolving 0.00% After 2 years of storage: - after 5 minutes of dissolving 0.04% - after 18 hours of dissolving 0.00%</p> <p><u>Dry sieve test</u> Method: CIPAC MT 59.1 Initial:</p> <table border="1" data-bbox="696 979 1077 1187"> <thead> <tr> <th>Fraction</th> <th>[%]</th> </tr> </thead> <tbody> <tr> <td>>1400 µm</td> <td>0.09</td> </tr> <tr> <td>1000 - 1400 µm</td> <td>91.88</td> </tr> <tr> <td>710 - 1000 µm</td> <td>6.54</td> </tr> <tr> <td>500 - 710 µm</td> <td>0.16</td> </tr> <tr> <td>300 - 500 µm</td> <td>0.08</td> </tr> <tr> <td><300 µm</td> <td>0.09</td> </tr> </tbody> </table> <p>After one year:</p> <table border="1" data-bbox="696 1214 1077 1422"> <thead> <tr> <th>Fraction</th> <th>[%]</th> </tr> </thead> <tbody> <tr> <td>>1400 µm</td> <td>0.13</td> </tr> <tr> <td>1000 - 1400 µm</td> <td>93.07</td> </tr> <tr> <td>710 - 1000 µm</td> <td>5.35</td> </tr> <tr> <td>500 - 710 µm</td> <td>0.16</td> </tr> <tr> <td>300 - 500 µm</td> <td>0.12</td> </tr> <tr> <td>45 - 300 µm</td> <td>1.03</td> </tr> </tbody> </table>	Fraction	[%]	>1400 µm	0.09	1000 - 1400 µm	91.88	710 - 1000 µm	6.54	500 - 710 µm	0.16	300 - 500 µm	0.08	<300 µm	0.09	Fraction	[%]	>1400 µm	0.13	1000 - 1400 µm	93.07	710 - 1000 µm	5.35	500 - 710 µm	0.16	300 - 500 µm	0.12	45 - 300 µm	1.03			<p>and physical-chemical and technical characteristic of formulation after storage for two years in ambient temperature are acceptable. Accepted</p>
Fraction	[%]																																	
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			<table border="1"> <tr> <td><45 µm</td> <td>0.16</td> </tr> </table> <p>After 2 years of storage:</p> <table border="1"> <tr> <td>Fraction</td> <td>[%]</td> </tr> <tr> <td>>1400 µm</td> <td>0.10</td> </tr> <tr> <td>1000 - 1400 µm</td> <td>94.28</td> </tr> <tr> <td>710 - 1000 µm</td> <td>3.93</td> </tr> <tr> <td>500 - 710 µm</td> <td>0.21</td> </tr> <tr> <td>300 - 500 µm</td> <td>0.16</td> </tr> <tr> <td>45 - 300 µm</td> <td>1.15</td> </tr> <tr> <td><45 µm</td> <td>0.17</td> </tr> </table> <p><u>Wet sieve test</u> Method: CIPAC MT 59.3 182 Initial:</p> <table border="1"> <tr> <td>Fraction</td> <td>[%]</td> </tr> <tr> <td>>125 µm</td> <td>0.06</td> </tr> <tr> <td>75-125 µm</td> <td>0.05</td> </tr> <tr> <td>63-75 µm</td> <td>0.03</td> </tr> <tr> <td>45-63 µm</td> <td>0.03</td> </tr> </table> <p>After 1 year: residue on 75 µm sieve 0.05% After 2 years of storage: residue on 75 µm sieve 0.04 %</p> <p><u>Dust content</u> Method: CIPAC MT 171 Initial: 0.0% 9.1 mg (0.03 %) After 1 year: 9.1 mg (0.03%) 2.5 mg (0.01 %) After 2 years of storage: 4.8 mg (0.02%)</p>	<45 µm	0.16	Fraction	[%]	>1400 µm	0.10	1000 - 1400 µm	94.28	710 - 1000 µm	3.93	500 - 710 µm	0.21	300 - 500 µm	0.16	45 - 300 µm	1.15	<45 µm	0.17	Fraction	[%]	>125 µm	0.06	75-125 µm	0.05	63-75 µm	0.03	45-63 µm	0.03			
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63-75 µm	0.03																																	
45-63 µm	0.03																																	
Shelf life in months (if less than 2 years) (KCP 2.7.6)			NA			Not applicable																												
Wettability (KCP 2.8.1)	CIPAC MT 53	TOTO 75 SG Batch No.:	0.1 and 2 years: Spontaneous	Y	Al Amin, Study code:	Previously accepted																												

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments				
		03.02.2011 Batch No.: TOTO/13.08.2010			BF-12/10 Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	(primary authorization No 104/2012 from 09.08.2012, with further changes)				
		TOTO 75 SG Batch No.: 03.02.2011	0. 1 and 2 years: Spontaneous (0s)	Y	Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	Accepted				
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	TOTO 75 SG Batch No.: 1905/15 Prod. date: 05.2015 Batch No.: TOTO/13.08.2010	10 ml after 10 s, 7 ml after 1 min, 6 ml after 3 min and 5 ml after 12 min. <table border="1" data-bbox="696 1169 1693 1278"> <tr> <td rowspan="2">Foaming</td> <td rowspan="2">CIPAC MT 47.2</td> <td>0.023% suspension: 6 ml after 10 s and 0 ml after 1 min, after 3 min and after 12 min</td> </tr> <tr> <td>0.045% suspension: 9 ml after 10 s, 7 ml after 1 min, 7 ml after 3 min and 5 ml after 12 min</td> </tr> </table>	Foaming	CIPAC MT 47.2	0.023% suspension: 6 ml after 10 s and 0 ml after 1 min, after 3 min and after 12 min	0.045% suspension: 9 ml after 10 s, 7 ml after 1 min, 7 ml after 3 min and 5 ml after 12 min	Y	Al Amin, Study code: BF-12/10 Al Amin, Study code: BF-78/15	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
Foaming	CIPAC MT 47.2	0.023% suspension: 6 ml after 10 s and 0 ml after 1 min, after 3 min and after 12 min								
		0.045% suspension: 9 ml after 10 s, 7 ml after 1 min, 7 ml after 3 min and 5 ml after 12 min								

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments			
	CIPAC MT 47.2	TOTO 75 SG Batch No.: 1905/15 Prod.date: 05.2015	<table border="1"> <tr> <td>Foaming</td> <td>CIPAC MT 47.2</td> <td> 0.023% suspension: 6 ml after 10 s and 0 ml after 1 min, after 3 min and after 12 min 0.045% suspension: 9 ml after 10 s, 7 ml after 1 min, 7 ml after 3 min and 5 ml after 12 min </td> </tr> </table>	Foaming	CIPAC MT 47.2	0.023% suspension: 6 ml after 10 s and 0 ml after 1 min, after 3 min and after 12 min 0.045% suspension: 9 ml after 10 s, 7 ml after 1 min, 7 ml after 3 min and 5 ml after 12 min	Y	Al Amin, Study code: BF-78/15	Accepted
Foaming	CIPAC MT 47.2	0.023% suspension: 6 ml after 10 s and 0 ml after 1 min, after 3 min and after 12 min 0.045% suspension: 9 ml after 10 s, 7 ml after 1 min, 7 ml after 3 min and 5 ml after 12 min							
Suspensibility (KCP 2.8.3.1)			NA			Not required			
Spontaneity of dispersion (KCP 2.8.3.2)			NA			Not required			
Dispersion stability (KCP 2.8.3.3)			NA			Not required			
Degree of dissolution and dilution stability (KCP 2.8.4)	Procedure no. SPR/BFC/ 11/b and CIPAC MT 179	TOTO 75 SG Batch No.: 03.02.2011 Batch No.: TOTO/13.08.2010	Initial and accelerated storage: No residue in a 75 µm sieve after 5 minutes and 18 hours after dissolving. After 1 year: after 5 minutes of dissolving 0.34 % after 18 hours of dissolving 0.00 % After 2 year: after 5 minutes of dissolving 0.04 % after 18 hours of dissolving 0.00 %	Y	Al Amin, Study code: BF-12/10 Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)			
		TOTO 75 SG Batch No.: 03.02.2011	After 1 year: after 5 minutes of dissolving 0.34 % - after 18 hours of dissolving 0.00 %	Y	Al Amin, Study code: BF-04/11, 2012	Results after 1 year of storage are acceptable			

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After 2 year: - after 5 minutes of dissolving 0.04 % - after 18 hours of dissolving 0.00 %			Accepted
					Al Amin, Study code: BF-04/11, 2013	Evaluation of 2 years storage results – see point KCP 2.7.5
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Procedure no. SPR/BF-C/18/b and CIPAC MT 59.1	TOTO 75 SG Batch No.: 03.02.2014 Batch No.: TOTO/13.08.2010	- Initial tested material: over 1400 µm 0.09 % between 1000 - 1400 µm 91.88 % between 710 - 1000 µm 6.54 % between 500 - 710 µm 0.16 % between 300 - 500 µm 0.08 % under 300 µm 1.25 % - After accelerated storage: over 1400 µm 0.13 % between 1000 - 1400 µm 92.73 % between 710 - 1000 µm 6.74 % between 500 - 710 µm 0.18 % between 300 - 500 µm 0.13 % under 300 µm 0.09 % After 1 year: over 1400 µm 0.13 % between 1000 - 1400 µm 93.07 %	Y	Al Amin, Study code: BF-12/10 Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>between 710 – 1000 µm 5.35 % between 500 – 710 µm 0.16 % between 300 – 500 µm 0.12 % between 45 – 300 µm 1.03 % under 45 µm 0.16 %</p> <p>After 2 year: over 1400 µm 0.10 % between 1000 – 1400 µm 94.28 % between 710 – 1000 µm 3.93 % between 500 – 710 µm 0.21 % between 300 – 500 µm 0.16 % between 45 – 300 µm 1.15 % under 45 µm 0.17 %</p>			
		TOTO 75 SG Batch No.: 03.02.2011	<p>After 1 year: over 1400 µm 0.13 % between 1000 - 1400 µm 93.07 % between 710 - 1000 µm 5.35 % between 500 - 710 µm 0.16 % between 300 - 500 µm 0.12 % between 45 - 300 µm 1.03 % under 45 µm 0.16 %</p> <p>After 2 year: over 1400 µm 0.10 % between 1000 - 1400 µm 94.28 % between 710 - 1000 µm 3.93 % between 500 - 710 µm 0.21 % between 300 - 500 µm 0.16 % between 45 - 300 µm 1.15 % under 45 µm 0.17 %</p>	Y	Al Amin, Study code: BF-04/11, 2012	Results after 1 year of storage are acceptable Accepted
					Al Amin, Study code: BF-04/11, 2013	Evaluation of 2 years storage results – see point KCP 2.7.5
Wet sieve test	CIPAC MT	TOTO 75 SG	Initial and accelerated storage:	Y	Al Amin,	Previously

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.1.2)	182	Batch No.: 03.02.2011 Batch No.: TOTO/13.08.2010	Fraction [%] >125 µm 0.06 75-125 µm 0.05 63-75 µm 0.03 45-63 µm 0.03 After 1 year: Residue on 75 µm sieve 0.05 % After 2 year: Residue on 75 µm sieve 0.04 %		Study code: BF-12/10 Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
		TOTO 75 SG Batch No.: 03.02.2011	After 1 year: Residue on 75 µm sieve 0.05 % After 2 year: Residue on 75 µm sieve 0.04 %	Y	Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	Results after 1 year of storage are acceptable Accepted Evaluation of 2 years storage results – see point KCP 2.7.5
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	TOTO 75 SG Batch No.: 03.02.2011 Batch No.: TOTO/13.08.2010	Initial: 9.1 mg (0.03 %) After 1 year: 2.5 mg (1 %) After 2 year: 4.8 mg (0.02 %) 0%	Y	Al Amin, Study code: BF-12/10 Al Amin, Study code: BF-04/11, 2012	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					Al Amin, Study code: BF-04/11, 2013	changes)
		TOTO 75 SG Batch No.: 03.02.2011	Initial: 9.1 mg (0.03 %) After 1 year: 2.5 mg (0.01 %) After 2 year: 4.8 mg (0.02 %)	Y	Al Amin, Study code: BF-04/11, 2012	Results after 1 year of storage are acceptable Accepted
					Al Amin, Study code: BF-04/11, 2013	Evaluation of 2 years storage results – see point KCP 2.7.5
Particle size of dust (KCP 2.8.5.2.2)			NA			Not required
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	TOTO 75 SG Batch No.: 1905/15 Prod.date: 05.2015	Average resistance to attrition 99.5%	Y	Al Amin, Study code: BF-78/15	Accepted
Hardness and integrity (KCP 2.8.5.4)			NA			Not required
Emulsifiability (KCP 2.8.6.1)			NA			Not required

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsion stability (KCP 2.8.6.2)			NA			Not required
Re-emulsifiability (KCP 2.8.6.3)			NA			Not required
Flowability (KCP 2.8.7.1)	CIPAC MT 172	TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	Average flowability 100%	Y	Al Amin, Study code: BF-12/10	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
Pourability (KCP 2.8.7.2)			NA			See point KCP 2.11
Dustability following accelerated storage (KCP 2.8.7.3)	CIPAC MT 171		0.0%	Y	Al Amin, Study code: BF-12/10 Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	Previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)

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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM E1518	TOTO 75 SG Batch No.: 0109/19-Z Prod. Date: 10/2019 Expiry date: 10/2021	All of the tank mixes: TOTO 75 SG + GALAPER 200 EC, TOTO 75 SG + GALAPER 200 EC + Asystemt +, TOTO 75 SG + GALAPER 200 EC + Partner+ , TOTO 75 SG + Asystemt+ and TOTO 75 SG + Partner+ are compatible.			Y	E. Arevalo, Study code: BF-05/21 BF-06/21 BF-07/21 BF-08/21 BF-09/21	Accepted Additionally, tank mixtures of TOTO 75 SG with Asystemt+, Partner+ and with GALAPER 200 EC were previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes)
Chemical compatibility of tank mixes (KCP 2.9.2)	SPB/215	TOTO 75 SG Batch No.: 0109/19-Z Prod. Date: 10/2019 Expiry date: 10/2021	Study	Method	Results	Y	Knapik, I. Study code: ICB/43/2021	Accepted Additionally, tank mixture of TOTO 75 SG with GALAPER 200 EC was previously accepted (primary authorization No 104/2012

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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			<p>Determination of active ingredients in 0.045% (w/v) solution of test item TOTO 75 SG</p>	SPB/215	<p>- thifensulfuron methyl – 6.93 [g/kg] - metsulfuron methyl – 0.69 [g/kg]</p>			from 09.08.2012, with further changes)
			<p>Determination of active ingredient in 0.3% (v/v) emulsion of test item GALAPER 200 EC</p>	SPB/215	<p>- fluroxypyr – 2.16 [g/L]</p>			
			<p>Chemical Compatibility Mixture 0.045% (w/v) of test item TOTO 75 SG and 0.3% (v/v) of test item GALAPER 200 EC</p>	SPB/215	<p>- thifensulfuron methyl – 6.81 [g/kg] - metsulfuron methyl – 0.703 [g/kg] - fluroxypyr – 2.11 [g/L]</p>			
			<p>Chemical compatibility with Asystent + and Partner + was determined by efficacy and residue trials where no abnormalities were found under assessment in the preparation of the spray liquid for the above mentioned studies and no problems were observed during the application of the agent.</p>					
			<p>Chemical compatibility with Asystent + and Partner + was determined by efficacy and</p>				Applicant's	Physical

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			residue trials where no abnormalities were found under assessment in the preparation of the spray liquid for the above-mentioned studies and no problems were observed during the application of the agent.		statement	compatibility of TOTO 75 SG with adjuvants – Asystem+ and with Partner+ was demonstrated (see point KCP 2.9.1). Additionally, tank mixtures of TOTO 75 SG with Asystem+ and with Partner+ were previously accepted (primary authorization No 104/2012 from 09.08.2012, with further changes) Accepted
Adhesion to seeds (KCP 2.10.1)			NA			Not required
Distribution to			NA			Not required

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																													
seed (KCP 2.10.2)																																			
Other/special studies (KCP 2.11)	GIFAP No. 17	TOTO 75 SG Batch No.: 03.02.2011	After initial and accelerated storage: White colour in HDPE-packages are stable After 1 year: White colour in HDPE-packages are stable After 2 year: White colour in HDPE-packages are stable	Y	Al Amin, Study code: BF-04/11, 2012 Al Amin, Study code: BF-04/11, 2013	See point KCP 2.7.5																													
	SPR/BF-C/22/b based on CIPAC MT 148.1	TOTO 75 SG Batch No.: TOTO/13.08.2010 Prod. Date: 13.08.2010	<table border="1"> <thead> <tr> <th>Tested material</th> <th></th> <th>Thifensulfuron methyl</th> <th>Metsulfuron methyl</th> </tr> </thead> <tbody> <tr> <td rowspan="5"><i>First rinsing water</i></td> <td>Concentration of the standard solution, [mg/ml]</td> <td>0.07</td> <td>0.005</td> </tr> <tr> <td>Average pick area of standard</td> <td>3211300</td> <td>354801</td> </tr> <tr> <td>Average pick area of tested sample</td> <td>1977140</td> <td>256906</td> </tr> <tr> <td>Content of active ingredient, [mg/ml]</td> <td>0.043</td> <td>0.004</td> </tr> <tr> <td>Content of active ingredient, [%]</td> <td>0.0043</td> <td>0.0004</td> </tr> <tr> <td rowspan="3"><i>Second rinsing water</i></td> <td>Concentration of the standard solution, [mg/ml]</td> <td>0.0064</td> <td>0.0005</td> </tr> <tr> <td>Average pick area of tested sample</td> <td>x</td> <td>x</td> </tr> <tr> <td>Content of active ingredient, [mg/ml]</td> <td>Nil</td> <td>Nil</td> </tr> </tbody> </table>	Tested material		Thifensulfuron methyl	Metsulfuron methyl	<i>First rinsing water</i>	Concentration of the standard solution, [mg/ml]	0.07	0.005	Average pick area of standard	3211300	354801	Average pick area of tested sample	1977140	256906	Content of active ingredient, [mg/ml]	0.043	0.004	Content of active ingredient, [%]	0.0043	0.0004	<i>Second rinsing water</i>	Concentration of the standard solution, [mg/ml]	0.0064	0.0005	Average pick area of tested sample	x	x	Content of active ingredient, [mg/ml]	Nil	Nil		Al Amin,, Study code: BF-12/10
Tested material		Thifensulfuron methyl	Metsulfuron methyl																																
<i>First rinsing water</i>	Concentration of the standard solution, [mg/ml]	0.07	0.005																																
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<i>Second rinsing water</i>	Concentration of the standard solution, [mg/ml]	0.0064	0.0005																																
	Average pick area of tested sample	x	x																																
	Content of active ingredient, [mg/ml]	Nil	Nil																																

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 Packaging and Compatibility with the Preparation (KCP 4.4)

TOTO 75 will be packed in High Density PolyEthylene (HDPE) containers having the size appropriate to hold either 40 g, 50g, 60g , 90g, 100g, 300g, 450 g, 600 g or 900 g of product, respectively. A description of the packaging and of the corresponding type of cap is given below:

HDPE JAR

40 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box.

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 64 mm/91.5 mm

Capacity: 188 ml overflow

Type of closure: screw-cap with seal

Size of opening: 46± 2 mm

Accessories: one measuring device per each jar

50 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box.

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 64 mm/91.5 mm

Capacity: 188 ml overflow

Type of closure: screw-cap with seal

Size of opening: 46± 2 mm

Accessories: one measuring device per each jar

60 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box.

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 64 mm/91.5 mm

Capacity: 188 ml overflow

Type of closure: screw-cap with seal

Size of opening: 46± 2 mm

Accessories: one measuring device per each jar

90 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box.

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 64 mm/91.5 mm

Capacity: 188 ml overflow

Type of closure: screw-cap with seal

Size of opening: 46± 2 mm

Accessories: one measuring device per each jar

100 g pack size

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The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 80 mm/138 mm

Capacity: 510 ml overflow

Type of closure: screw-cap with seal

Size of opening: 46± 2 mm

Accessories: one measuring device per each jar

300 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 81 mm/149.1 mm

Capacity: 600 ml overflow

Type of closure: screw-cap with seal

Size of opening: 72 mm minimum

Accessories: one measuring device per each jar

450 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 108 mm/226.3 mm

Capacity: 2000 ml overflow

Type of closure: screw-cap with seal

Size of opening: 46 mm minimum

Accessories: one measuring device per each jar

450 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 122 mm/220.2 mm

Capacity: 2000 ml overflow

Type of closure: screw-cap with seal

Size of opening: 93 mm minimum

Accessories: one measuring device per each jar

600 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 108 mm/226.3 mm

Capacity: 2000 ml overflow

Type of closure: screw-cap with seal

Size of opening: 46 mm minimum

Accessories: one measuring device per each jar

600 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 122 mm/220.2 mm

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Capacity: 2000 ml overflow

Type of closure: screw-cap with seal

Size of opening: 93 mm minimum

Accessories: one measuring device per each jar

900 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 108 mm/226.3 mm

Capacity: 2000 ml overflow

Type of closure: screw-cap with seal

Size of opening: 46 mm minimum

Accessories: one measuring device per each jar

900 g pack size

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box

Material: HDPE

Type of construction: jar

Size: approximate diameter/height: 122 mm/220.2 mm

Capacity: 2000 ml overflow

Type of closure: screw-cap with seal

Size of opening: 93 mm minimum

Accessories: one measuring device per each jar

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 2.2.1.1	Salacinski T.	2010	TOTO 75 SG - Determination of explosive properties. Institute of Industrial Organic Chemistry, Department of Highenergetic Materials, 6 Annopol Str., 03-236 Warsaw, Poland Study Code: BW-08/10 Report to GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.2.2. KCP 2.3.1 KCP 2.3.2 KCP 2.3.3	Fraczak M.	2010	TOTO 75 SG Determination of relative self-ignition temperature, flammability and oxidizing properties. Institute of Industrial Organic Chemistry, Chemical Safety and Electrostatics Division, 6 Annopol Str., 03-236 Warsaw, Poland Study Code: BC-27/10 Report to GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.1 KCP 2.4.1 KCP 2.6.2 KCP 2.71 KCP 2.7.3 KCP 2.7.5	Al Amin I.	2010	TOTO 75 SG Part I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry, Pesticides Application and Formulation Department, 6 Annopol Str., 03-236 Warsaw, Poland Study code no. BF-12/10 Report to GLP Unpublished	N	Chemirol Sp. z o.o.

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KCP 2.8.1 KCP 2.84					
KCP 2.8.7.2 KCP 2.11	Al Amin I.	2010	TOTO 75 SG Part I: Determination of physicochemical properties of the initial preparation Effectiveness of package cleaning Institute of Industrial Organic Chemistry, Pesticides Application and Formulation Department, 6 Annopol Str., 03-236 Warsaw, Poland Study code no. BF-12/10 Report to GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 2.1 KCP 2.4.1 KCP 2.7.5 KCP 2.8.4 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.7.1 KCP 2.8.7.3	Al Amin I.	2011	TOTO 75 SG Part II: Determination of physicochemical properties of the preparation after nine months storage at ambient temperature Institute of Industrial Organic Chemistry, Pesticides Application and Formulation Department, 6 Annopol Str., 03-236 Warsaw, Poland Study code no. BF-04/11 Report to GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 2.1 KCP 2.4.1 KCP 2.7.5 KCP 2.8.4 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.7.1	Al Amin I.	2012	TOTO 75 SG Part III: Determination of physicochemical properties after the first year of storage Institute of Industrial Organic Chemistry, Pesticides Application and Formulation Department, 6 Annopol Str., 03-236 Warsaw, Poland Study code no. BF-04/11 Report to GLP Unpublished	N	Chemiroł Sp. z o.o.

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KCP 2.8.7.3 KCP 2.11					
KCP 2.1 KCP 2.4.1 KCP 2.7.5 KCP 2.8.4 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.7.1 KCP 2.8.7.3 KCP 2.11	Al Amin I.	2013	TOTO 75 SG Part III IV: Determination of physicochemical properties after the second year of storage Institute of Industrial Organic Chemistry, Pesticides Application and Formulation Department, 6 Annopol Str., 03-236 Warsaw, Poland Study code no. BF-04/11 Report to GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 2.8.2 KCP 2.8.5.3	Al Amin I.	2015	TOTO 75 SG Determination of attrition resistance and persistent foaming Institute of Industrial Organic Chemistry, Pesticides Application and Formulation Department, 6 Annopol Str., 03-236 Warsaw, Poland Study code no. BF-78/15 Report to GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 2.9.1	E. Arevalo	2021	TOTO 75 SG + Galaper 200 EC Evaluation of physical compatibility Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland Study code no. BF-05/21 Report to GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 2.9.1	E. Arevalo	2021	TOTO 75 SG + Galaper 200 EC + Asystem + Evaluation of physical compatibility Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland	N	Chemiroł Sp. z o.o.

TOTO 75 SG/ TOTO 75 SG, TYTAN 75 SG, HERKULES 75 SG

Part B – Section 1, 2 and 4 - Core Assessment

Applicant version

			Study code no. BF-06/21 Report to GLP Unpublished		
KCP 2.9.1	E. Arevalo	2021	TOTO 75 SG + Galaper 200 EC + Partner+ Evaluation of physical compatibility Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland Study code no. BF-07/21 Report to GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.9.1	E. Arevalo	2021	TOTO 75 SG + Asyent+ Evaluation of physical compatibility Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland Study code no. BF-08/21 Report to GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.9.1	E. Arevalo	2021	TOTO 75 SG + Partner+ Evaluation of physical compatibility Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland Study code no. BF-09/21 Report to GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.9.2	Knapik, I.	2021	Determination of physicochemical properties ICB Pharma, Lema 10, Street, 43-600, Jaworzno, POLAND Study code: ICB/43/2021 GLP Unpublished	N	Chemirol Sp. z o.o.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status	Vertebrate study Y/N	Owner
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TOTO 75 SG/ TOTO 75 SG, TYTAN 75 SG, HERKULES 75 SG
 Part B – Section 1, 2 and 4 - Core Assessment
 Applicant version

			Published or not		
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The following tables are to be completed by MS.

List of data submitted by the applicant and not 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

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

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