

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: TERBUT 500 SC

Product name(s): La Zina 500 SC; Tekno 500 SC

Chemical active substance(s):

Tertbutylazine, 500 g/L or g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: PUH Chemirol Sp. z o.o.

Submission date: November 2019

MS Finalisation date: November 2021; June 2022

Version history

When	What
November 2021	RMS finalised dRR assessment
June 2022	Final Version after Commenting period

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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:

- none.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: PUH Chemirol Sp. z o.o.
Address: Przemyslowa 3 Street, 88-300 Mogilno, 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

Producer of the preparation

Name PUH Chemirol Sp. z o.o.
Address PUH Chemirol Sp. z o.o.
Ul. Przemyslowa 3
88-300 Mogilno, Poland

Location of the manufacturing site

CONFIDENTIAL information - data 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 Terbutylazine

According to *Terbutylazine SANCO/11337/2011 rev 2 17 June 2011*

Terbutylazine min. 950 g/kg

Impurities

Propazine max. 10 g/kg
Atrazine max. 1 g/kg
Simazine max. 30 g/kg

Comment of zRMS:	The active ingredient source used is approved at EU level with a minimum purity of 950 g/kg.
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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: La Zina 500 SC; Tekno 500 SC
 Company code number: TERBUT 500 SC

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)
Terbutylazine	500 g/L	475 – 525	491 – 541 500 – 552.6	44.43 – 48.96 45.25 – 50.01

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

** Based on the density of the formulation = 1.105 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Propazine	10 g/kg
Atrazine	1 g/kg
Simazine	30 g/kg

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

Table 1.4-3: Information on terbutylazine

Type	Name/Code Number	
ISO common name	Terbutylazine	
CAS No.	5915-41-3	
EEC No.	227-637-9	
CIPAC No.	234	

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: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

TERBUT 500 SC is herbicide formulation.

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 homogenous white liquid, with a characteristic odour. It is not explosive, has no oxidising properties. In aqueous solution, it has a pH value around 7.76 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. 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 *SC* formulation.

The intended concentration of use is ~~0.26%~~ 0.25% to 0.75%.

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 TERBUT 500 SC complies with FAO specification 234/SC/S (1991).

Formulation used for tests

Terbut 500 SC
Batch No.: 1/18
Production date: 01.2018

Terbut 500 SC
Batch No.: 7/17
Production date: 04.2017

Terbut 500 SC
Batch No.: 01/2020
Production date: 01.2020

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)		Terbut 500 SC Batch No.: 1/18	Initial preparation: Homogenous white liquid of characteristic odour After accelerated storage: Homogenous white liquid of characteristic odour After 0°C: Homogenous white liquid of characteristic odour After the first year: Homogenous white liquid of characteristic odour After the second year: Homogenous white liquid of characteristic odour	Y	Al Amin, I., Study code: BF-07/18, 2018 Al Amin, I., Study code: BF-07/18, 2019 E.Arevalo, Study code: BF-07/18, 2020	Accepted.
Explosive properties (KCP 2.2.1)	EEC A.14	Terbut 500 SC Batch No.: 1/18	Terbut 500 SC does not have explosive properties according to the criteria of EEC a.14 method.	Y	Śliwa, P., Study code: BW-14/18, 2018	In thermal sensitivity test no explosion occurred. In impact sensitivity test no explosion occurred. Accepted.
Oxidizing properties (KCP 2.2.2)	-	-	Formulation type of Terbut 500 SC is a concentrated soluble suspension water, the main ingredients are terbuthylazine (45.86 %) and water (45.33 %). Main components: terbuthylazine and water are defined as not having oxidizing properties and other components which are less than 5% are defined as not having oxidizing properties too.	-	-	Accepted.
Flash point (KCP 2.3.1)	EEC A.19 A.9	Terbut 500 SC	Terbut 500 SC has not got the flash point up to the boiling point according to A.9 method.	Y	Flasińska, P., Study	The test was performed with

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No.: 1/18			code: BC-31/18, 2018	Pensky-Martens apparatus. The formulation is not flammable. Accepted.
Flammability (KCP 2.3.2)	-	-	Since Terbut 500 SC is a suspension concentrate (SC) which is based mainly on water suspension, it is not expected to be flammable.	-	-	Not required for liquid formulations.
Self-heating (KCP 2.3.3)	EEC A.15	Terbut 500 SC Batch No.: 1/18	Terbut 500 SC has not got the auto-ignition temperature up to 650°C according to A.15 method	Y	Flasińska, P., Study code: BC-31/18, 2018	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	N/R See point KCP 2.4.2	-	-	
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Terbut 500 SC Batch No.: 1/18 Terbut 500 SC Batch No.: 01/2020	Initial preparation: pH 1%= 7.76 undiluted: 7.11 After accelerated storage: pH 1%=7.49 undiluted: 6.75 After the one year storage: pH 1%= 7.46 After the second year storage: pH 1%= 7.60 Undiluted: 7.14	Y	Al Amin, I., Study code: BF-07/18, 2018 Al Amin, I., Study code: BF-07/18, 2019 E.Arevalo, Study code: BF-07/18, 2020 E. Arevalo,	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments															
					Study code: BF-07/20, 2020																
Viscosity (KCP 2.5.1)	OECD 114	Terbut 500 SC Batch No.: 1/18	<table border="0"> <tr> <td></td> <td>at 20°C:</td> <td>at 40°C:</td> </tr> <tr> <td>- at shear rate of 2.5 s-1</td> <td>1875 mPa·s,</td> <td>1603 mPa·s,</td> </tr> <tr> <td>- at shear rate of 5.0 s-1</td> <td>1112 mPa·s,</td> <td>950 mPa·s,</td> </tr> <tr> <td>- at shear rate of 10 s-1</td> <td>668 mPa·s,</td> <td>563 mPa·s,</td> </tr> <tr> <td>- at shear rate of 25 s-1</td> <td>354 mPa·s,</td> <td>292 mPa·s,</td> </tr> </table>		at 20°C:	at 40°C:	- at shear rate of 2.5 s-1	1875 mPa·s,	1603 mPa·s,	- at shear rate of 5.0 s-1	1112 mPa·s,	950 mPa·s,	- at shear rate of 10 s-1	668 mPa·s,	563 mPa·s,	- at shear rate of 25 s-1	354 mPa·s,	292 mPa·s,	Y	Al Amin, I., Study code: BF-07/18, 2018	The formulation is non-Newtonian liquid. Accepted.
	at 20°C:	at 40°C:																			
- at shear rate of 2.5 s-1	1875 mPa·s,	1603 mPa·s,																			
- at shear rate of 5.0 s-1	1112 mPa·s,	950 mPa·s,																			
- at shear rate of 10 s-1	668 mPa·s,	563 mPa·s,																			
- at shear rate of 25 s-1	354 mPa·s,	292 mPa·s,																			
Surface tension (KCP 2.5.2)	EEC A.5	Terbut 500 SC Batch No.: 1/18	43.23 mN/m	Y	Al Amin, I., Study code: BF-07/18, 2018	The study was performed at 20.0°C. The highest recommended use concentration is 0.5% v/v. The study was performed with a concentration higher than the maximum recommended concentration (0.75% v/v). The preparation is surface-active. Accepted.															
Relative density (KCP 2.6.1)	CIPAC MT 3.2	Terbut 500 SC Batch No.: 1/18	At 20°C: absolute 1.105 g/ml, relative 1.105 At 40°C: absolute 1.097 g/ml, relative 1.097	Y	Al Amin, I., Study code: BF-07/18, 2018	Accepted.															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
other periods and/or temperatures (KCP 2.7.2)						
Minimum content after heat stability testing (KCP 2.7.3)	HPLC	Terbut 500 SC Batch No.: 1/18 Batch No.: 01/20	Initial preparation: Terbutylazine – 46.20% (510.51 g/l) Atrazine - < LOQ Propazine - < LOQ Simazine 0.0387% (0.4276 g/l) After accelerated storage: Terbutylazine – 46.83% (517.47 g/l) Atrazine - < LOQ Propazine - < LOQ Simazine – 0.038% (0.4169 g/l) After accelerated storage: Terbutylazine – 45.99% (509.1 g/l). After the first year: Terbutylazine – 46.52% (514.1 g/l) Atrazine - < LOQ Propazine – 0.0045% (0.049 g/l) Simazine – 0.045 (0.497 g/l) After the second year: Terbutylazine – 46.79% (517.1 g/l) Atrazine - < LOQ Propazine - < LOQ Simazine – 0.035% (0.387 g/l)	Y	Al Amin, I., Study code: BF-07/18, 2018 E.Arevalo, Study code: BF-07/18, 2020 Al Amin, I., Study code: BF-07/18, 2019 E.Arevalo, Study code: BF-07/18, 2020	LOQ for atrazine - 0.0002% LOQ for propazine - 0.0004%. Accepted.
Effect of low temperatures on stability	CIPAC MT 39.3	Terbut 500 SC Batch No.:	Homogenous white liquid	Y	Al Amin, I., Study code: BF-07/18,	The test temperature varied between

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.4)		1/18			2018	0.4°C to 0.1°C. No changes to colour and physical state nor to technical properties (suspensibility, wet sieve test results) were noted. Accepted.
	CIPAC MT 39.3 CIPAC MT 160	Terbut 500 SC Batch No.: 01/2020	Homogenous liquid Spontaneity of dispersion: 87.5%	Y	Zieliński, J., Study code: BF-49/21, 2021	The test temperature varied between -0.8°C to 0.1°C. No change to colour and physical state. The result of spontaneity of dispersion test was within limits. Accepted.

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments																																																																
Ambient temperature shelf life (KCP 2.7.5)		Terbut 500 SC Batch No.: 1/18 Batch No.: 01/2020	<table border="1"> <thead> <tr> <th rowspan="2">Test Type</th> <th rowspan="2">Methods</th> <th colspan="3">Findings</th> </tr> <tr> <th>Initial preparation, 2018</th> <th>After the first year, 2019</th> <th>After the second year, 2020</th> </tr> </thead> <tbody> <tr> <td>Physical state colour and odour</td> <td>Organoleptic</td> <td>Homogenous white liquid of characteristic odour</td> <td>Homogenous white liquid of characteristic odour</td> <td>Homogenous white liquid of characteristic odour</td> </tr> <tr> <td rowspan="2">pH</td> <td>1%</td> <td>CIPAC MT 75.3</td> <td>7.76</td> <td>7.46</td> <td>7.60</td> </tr> <tr> <td>Undiluted</td> <td></td> <td>-</td> <td>-</td> <td>7.14</td> </tr> <tr> <td rowspan="3">Suspension stability</td> <td>0.8 l. in 300 l</td> <td rowspan="3">CIPAC MT 184</td> <td>100.31%</td> <td>99.46%</td> <td>100.62%</td> </tr> <tr> <td>1.5 l. in 200 l</td> <td>99.61%</td> <td>100.28%</td> <td>100.07%</td> </tr> <tr> <td>0.2 %</td> <td>-</td> <td>-</td> <td>99.69%</td> </tr> <tr> <td>Dispersion spontaneity</td> <td>CIPAC MT 160</td> <td>84.57%</td> <td>87.21%</td> <td>90.17%</td> </tr> <tr> <td>Wet sieve test</td> <td>CPAC MT 185</td> <td>0.00 %</td> <td>0.00%</td> <td>0.00%</td> </tr> <tr> <td>Pourability</td> <td>CIPAC MT 148.1</td> <td>R = 5.53%, R' = 0.39%</td> <td>R = 3.60%, R' = 0.24%</td> <td>R = 3.17%, R' = 0.37%</td> </tr> <tr> <td>Particle size distribution</td> <td>CIPAC MT 187</td> <td>d₁₀ = 0.61 µm, d₅₀ = 2.11 µm, d₉₀ = 5.76 µm d_{4,3} = 2.72 µm SD = 0.013 µm, RSD = 0.478%</td> <td>d₁₀ = 0.56 µm, d₅₀ = 1.94 µm d₉₀ = 5.39 µm, d_{4,3} = 2.51 µm SD = 0.044 µm, RSD = 1.75%</td> <td>d₁₀ = 0.608 µm, d₅₀ = 2.107 µm d₉₀ = 5.758 µm, d_{4,3} = 2.719 µm SD = 0.011 µm, RSD = 0.42%</td> </tr> <tr> <td>Package stability</td> <td>CropLife International Technical Monograph No. 17</td> <td>White cylindrical HDPE bottles</td> <td>Stable, white cylindrical HDPE bottles</td> <td>Stable, white cylindrical HDPE bottles</td> </tr> <tr> <td>Active ingredient and relevant impurities</td> <td>HPLC</td> <td>Terbutylazine 46.20% (510.51 g/l) Atrazine and propazine < LOQ Simazine 0.0387% (0.4276 g/l)</td> <td>Terbutylazine 46.52% (514.1 g/l) Atrazine < LOQ, Propazine 0.0045% (0.049 g/l), Simazine 0.045% (0.497 g/l)</td> <td>Terbutylazine 46.79% (517.1 g/l) Atrazine and Propazine < LOQ Simazine 0.035% (0.387 g/l)</td> </tr> </tbody> </table>	Test Type	Methods	Findings			Initial preparation, 2018	After the first year, 2019	After the second year, 2020	Physical state colour and odour	Organoleptic	Homogenous white liquid of characteristic odour	Homogenous white liquid of characteristic odour	Homogenous white liquid of characteristic odour	pH	1%	CIPAC MT 75.3	7.76	7.46	7.60	Undiluted		-	-	7.14	Suspension stability	0.8 l. in 300 l	CIPAC MT 184	100.31%	99.46%	100.62%	1.5 l. in 200 l	99.61%	100.28%	100.07%	0.2 %	-	-	99.69%	Dispersion spontaneity	CIPAC MT 160	84.57%	87.21%	90.17%	Wet sieve test	CPAC MT 185	0.00 %	0.00%	0.00%	Pourability	CIPAC MT 148.1	R = 5.53%, R' = 0.39%	R = 3.60%, R' = 0.24%	R = 3.17%, R' = 0.37%	Particle size distribution	CIPAC MT 187	d ₁₀ = 0.61 µm, d ₅₀ = 2.11 µm, d ₉₀ = 5.76 µm d _{4,3} = 2.72 µm SD = 0.013 µm, RSD = 0.478%	d ₁₀ = 0.56 µm, d ₅₀ = 1.94 µm d ₉₀ = 5.39 µm, d _{4,3} = 2.51 µm SD = 0.044 µm, RSD = 1.75%	d ₁₀ = 0.608 µm, d ₅₀ = 2.107 µm d ₉₀ = 5.758 µm, d _{4,3} = 2.719 µm SD = 0.011 µm, RSD = 0.42%	Package stability	CropLife International Technical Monograph No. 17	White cylindrical HDPE bottles	Stable, white cylindrical HDPE bottles	Stable, white cylindrical HDPE bottles	Active ingredient and relevant impurities	HPLC	Terbutylazine 46.20% (510.51 g/l) Atrazine and propazine < LOQ Simazine 0.0387% (0.4276 g/l)	Terbutylazine 46.52% (514.1 g/l) Atrazine < LOQ, Propazine 0.0045% (0.049 g/l), Simazine 0.045% (0.497 g/l)	Terbutylazine 46.79% (517.1 g/l) Atrazine and Propazine < LOQ Simazine 0.035% (0.387 g/l)		Al Amin, I., Study code: BF-07/18, 2018 Al Amin, I., Study code: BF-07/18, 2019 E.Arevalo, Study code: BF-07/18, 2020 E. Arevalo, Study code: BF-07/20, 2020	The tested material was stored in 1 liter HDPE bottles. The storage temperature varied between 18.2°C and 21.8°C. After the storage: - the change in the a.s. content after 2 years was 1,3% - the change in the simazine (RI) content after 2 years was 9.6% - no change in the sample appearance, colour or odour - no significant changes in technical properties - no significant changes to containers (weight, appearance) As, according to
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Particle size distribution	CIPAC MT 187	d ₁₀ = 0.61 µm, d ₅₀ = 2.11 µm, d ₉₀ = 5.76 µm d _{4,3} = 2.72 µm SD = 0.013 µm, RSD = 0.478%	d ₁₀ = 0.56 µm, d ₅₀ = 1.94 µm d ₉₀ = 5.39 µm, d _{4,3} = 2.51 µm SD = 0.044 µm, RSD = 1.75%	d ₁₀ = 0.608 µm, d ₅₀ = 2.107 µm d ₉₀ = 5.758 µm, d _{4,3} = 2.719 µm SD = 0.011 µm, RSD = 0.42%																																																																						
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Initial preparation: pH undiluted: 7.11 Suspension stability 0.2%: 99.89																																																																										

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						“Guidance document for the generation of data on the physical, chemical and technical properties of plant protection products” under Regulation (EC) No. 1107/2009: “For aqueous based formulation types extrapolation between any plastic material types is acceptable” the containers are acceptable for packaging of the formulation. Accepted.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	N/R	-	-	
Wettability (KCP 2.8.1)	-	-	N/R	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Terbut 500 SC Batch No.: 1/18 Terbut 500 SC Batch No.: 01/2020	Foam 1,5 liter in 200 l: 10 ml after 1 min and 7 ml after 12 min Persistent foam (0.26%): After 1 min – 0ml, After 12 min – 0 ml	Y	Al Amin, I., Study code: BF-07/18, 2018 E. Arevalo, Study code: BF-07/20, 2020	The recommended use concentrations are 0.25% and 0.5% v/v. The studies were performed with concentrations higher than the maximum recommended concentration (0.75% v/v) and close to minimal recommended concentration (0.26% v/v). CIPAC water D was used. Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Terbut 500 SC Batch No.: 1/18 Terbut 500 SC Batch No.: 01/2020	Initial preparation: 0.8 liter in 300 liter: 100.31% 1.5 liter in 200 liter: 99.61% 0.2%: 99.89% After accelerated storage: 0.8 liter in 300 liter: 101.58% 1.5 liter in 200 liter: 100.69% 0.2%: 97.15% After storage 0°C:	Y	Al Amin, I., Study code: BF-07/18, 2018 Al Amin, I., Study code: BF-07/18, 2019 E. Arevalo,	The recommended use concentrations are 0.25% and 0.5% v/v. The studies were performed with concentrations higher than the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			0.8 liter in 300 liter: 101.22% 1.5 liter in 200 liter: 100.71% After the first year: 0.8 liter in 300 liter: 99.46% 1.5 liter in 200 liter: 100.28% After the second year storage: 0.8 liter in 300 liter: 100.62 % 1.5 liter in 200 liter: 100.07% 0.2%: 99.69%		Study code: BF-07/18, 2020 E. Arevalo, Study code: BF-07/20, 2020	maximum recommended concentration (0.75% v/v) and close to minimal recommended concentration (0.2% and 0.26% v/v). Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	N/R	-	-	
Dispersion stability (KCP 2.8.3.3)	CIPAC MT 160	Terbut 500 SC Batch No.: 1/18	Initial preparation: 84.57% After accelerated storage: 94.33% After the first year: 87.21% After the second year: 90.17%	Y	Al Amin, I., Study code: BF-07/18, 2018 Al Amin, I., Study code: BF-07/18, 2019 E. Arevalo, Study code: BF-07/18, 2020	The test was performed with standard water D at 30°C. Accepted.
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	N/R	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	Terbut 500 SC Batch No.: 1/18	Initial preparation: $d_{10} = 0.61 \mu\text{m}$, $d_{50} = 2.11 \mu\text{m}$, $d_{90} = 5.76 \mu\text{m}$ $d_{4,3} = 2.72 \mu\text{m}$ $SD = 0.013 \mu\text{m}$, $RSD = 0.478\%$ After accelerated storage: $d_{10} = 0.64 \mu\text{m}$, $d_{50} = 2.24 \mu\text{m}$ $d_{90} = 5.92 \mu\text{m}$, $d_{4,3} = 2.82 \mu\text{m}$ $SD = 0,029 \mu\text{m}$, $RSD = 1.021\%$ After the first year: $d_{10} = 0.56 \mu\text{m}$, $d_{50} = 1.94 \mu\text{m}$ $d_{90} = 5.39 \mu\text{m}$, $d_{4,3} = 2.51 \mu\text{m}$ $SD = 0,044 \mu\text{m}$, $RSD = 1.75\%$ After the second year: $d_{10} = 0.608 \mu\text{m}$, $d_{50} = 2.107 \mu\text{m}$ $d_{90} = 5.758 \mu\text{m}$, $d_{4,3} = 2.719 \mu\text{m}$ $SD = 0,011 \mu\text{m}$, $RSD = 0.42\%$	Y	Al Amin, I., Study code: BF-07/18, 2018 Al Amin, I., Study code: BF-07/18, 2019 E.Arevalo, Study code: BF-07/18, 2020	Determination of the particle size was performed with the laser diffraction method. Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Terbut 500 SC Batch No.: 1/18	Initial preparation: Residue in 75 μm sieve: 0.00% After accelerated storage: Residue in 75 μm sieve: 0.75%	Y	Al Amin, I., Study code: BF-07/18, 2018	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After storage 0°C: Residue in 75 µm sieve: 0.00% After the first year storage: Residue in 75 µm sieve: 0.00% After the first year storage: Residue in 75 µm sieve: 0.00%		Al Amin, I., Study code: BF-07/18, 2019 E.Arevalo, Study code: BF-07/18, 2020	
Dust content (KCP 2.8.5.2.1)	-	-	N/R	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	N/R	-	-	
Attrition (KCP 2.8.5.3)	-	-	N/R	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	N/R	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	N/R	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	N/R	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	N/R	-	-	
Flowability (KCP 2.8.7.1)	-	-	N/R	-	-	
Pourability	CIPAC MT	Terbut 500	Initial preparation:	Y	Al Amin, I.,	The acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.7.2)	148.1	SC Batch No.: 1/18	R= 5.53% and R'= 0.39% After accelerated storage: R= 4.22% and R'=0.35% After the first year: R= 3.60% and R'=0.24% After the second year: R= 3.17% and R'=0.37%		Study code: BF-07/18, 2018 Al Amin, I., Study code: BF-07/18, 2019 E.Arevalo, Study code: BF-07/18, 2020	limit for residue is 5%. Initial formulation exceed this value slightly. Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	N/R	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM E 1518 – 05	Terbut 500 SC Batch No.: 01/2020	N/R The determination of compatability was performed for Terbut 500 SC and adjuvant Hydravance 100-LQ. The study was carried out for four mixtures of test items in Standard Water C (hadrness 500 ppm) at ambient temperature: - mixture I: 0.27% (v/v) Terbut 500 SC and 0.06% (v/v) Hydravance 100-LQ - mixture II: 0.27% (v/v) Terbut 500 SC and 0.1% (v/v) Hydravance 100-LQ - mixture III: 0.5% (v/v) Terbut 500 SC and 0.06% (v/v) Hydravance 100-LQ - mixture IV: 0.5% (v/v) Terbut 500 SC and 0.1% (v/v) Hydravance 100-LQ The components of all mixtures are compatible – no residue remained on the 300 µm sieve.	Y	I. Knapik, Study code: ICB/119/20 20, 2020	Accepted.
Chemical compatibility of tank mixes (KCP 2.9.2)	ASTM E 1518 – 05	Terbut 500 SC Batch No.: 01/2020	N/R The chemical compatibility of tank mix of Terbut 500 SC with adjuvant Hydravance 100 LQ was assessed during the efficacy/fitotoxicity field trials (Study code: SRPL19-147-336 HE - SRPL19-154-336HE; SGS/2017/145/PL01-06; SGS-2017-H-001-GER01-05; SGS-2017-H-001-CZ01; AH/19/K/14/Ce/04; AH/19/K/14/Dziem/03; AH/19/K/14/Gr/01; AH/19/K/14/Nw/01;	-	Applicant statement.	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																														
			AH/19/K/14/Nw/05; AH/19/K/14/Ra/02; SPRL19-155-336HS do SPRL19-159-336HS; AH/19/K/14/BR/2; AH/19/K/14/GR/5; AH/19/K/14/NW/1; AH/19/K/14/RA/4; AH/19/K/14/ZL/3). Neither during the mixing process, application nor sample analysis the problems with the compatility were observed.																																	
Adhesion to seeds (KCP 2.10.1)	-	-	N/R	-	-																															
Distribution to seed (KCP 2.10.2)	-	-	N/R	-	-																															
Other/special studies (KCP 2.11)	GIFAP No. 17	Terbut 500 SC Batch No.: 1/18 Terbut 500 SC Batch No.: 01/2020	Initial preparation: White cylindrical HDPE bottles After accelerated storage: Stable, white cylindrical HDPE bottles After the first year: Stable, white cylindrical HDPE bottles After the second year: Stable, white cylindrical HDPE bottles	Y	Al Amin, I., Study code: BF-07/18, 2019 E.Arevalo, Study code: BF-07/18, 2020	Accepted.																														
	SPO/BF/22/b Efficacy Guideline 305:2004	Terbut 500 SC Batch No.: 01/2020	<table border="1"> <thead> <tr> <th>Application equipment cleaning</th> <th>SPO/BF/22/b Efficacy Guideline 305: 2004</th> <th>Bottle Nr.</th> <th>Water used [ml]</th> <th>s.a charged [mg]</th> <th>s.a. removed [mg]</th> <th>Efectiveness [%]</th> <th>Avg. [%]</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td>1</td> <td>10</td> <td>340.5</td> <td>80</td> <td>76.51</td> <td rowspan="3">91.49</td> </tr> <tr> <td></td> <td></td> <td>2</td> <td>2 x 10</td> <td>340.5</td> <td>6</td> <td>98.24</td> </tr> <tr> <td></td> <td></td> <td>3</td> <td>3 x 10</td> <td>340.5</td> <td>1</td> <td>99.71</td> </tr> </tbody> </table>	Application equipment cleaning	SPO/BF/22/b Efficacy Guideline 305: 2004	Bottle Nr.	Water used [ml]	s.a charged [mg]	s.a. removed [mg]	Efectiveness [%]	Avg. [%]			1	10	340.5	80	76.51	91.49			2	2 x 10	340.5	6	98.24			3	3 x 10	340.5	1	99.71	Y	E. Arevalo, Study code: BF-07/20, 2020	Bottle 1 was rinsed once, bottle 2 was rinsed twice and bottle 3 was rinsed three times. Accepted.
Application equipment cleaning	SPO/BF/22/b Efficacy Guideline 305: 2004	Bottle Nr.	Water used [ml]	s.a charged [mg]	s.a. removed [mg]	Efectiveness [%]	Avg. [%]																													
		1	10	340.5	80	76.51	91.49																													
		2	2 x 10	340.5	6	98.24																														
		3	3 x 10	340.5	1	99.71																														

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)

Comment of zRMS:	In the accelerated stability study and shelf-life study the formulation has been tested in its original HDPE bottles and the packaging remained stable. Since the formulation is SC formulation, it is possible, according to the guideline of Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin), to extrapolate the results to other plastic packaging, therefore, also the other proposed commercial packs are considered acceptable.
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Table 4.1-1: Packaging information

Type	JAR
Material:	HDPE
size:	63/64 mm / 91,5 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	188 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information

Type	BOTTLE
Material:	HDPE
size:	64 mm± 2 mm/130 mm ± 3 mm
Opening:	40 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information

Type	BOTTLE
Material:	HDPE
size:	72 mm± 2 mm/111,8 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-4: Packaging information

Type	BOTTLE
Material:	HDPE
size:	72±1 mm/111.8±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information

Type	BOTTLE
Material:	HDPE
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.65± 2 mm
Closure:	screw cap with seal
Capacity	564 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information

Type	BOTTLE
Material:	HDPE
size:	90,5 mm± 2 mm/151 mm ± 3 mm
Opening:	40,6 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information

Type	BOTTLE
Material:	HDPE
size:	77,6 mm± 2 mm/160,6 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information

Type	BOTTLE
Material:	HDPE
size:	77.6 ±1 mm/160.6±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information

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 mm minimum
Accessories: one measuring device per each jar

Table 4.1-10: Packaging information

Type	BOTTLE
Material:	HDPE
size:	145.5mm± 2 mm/78mm ± 2 mm
Opening:	56mm ± 2 mm
Closure:	screw cap with seal
Capacity	600 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information

Type	JAR
Material:	HDPE
size:	79/80 mm/ 201 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	800 ml

Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information

Type	BOTTLE
Material:	HDPE
size:	80 mm± 2 mm/201 mm ± 2 mm
Opening:	64 mm
Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information

Type	BOTTLE
Material:	HDPE
size:	88.5 mm± 2 mm/283.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-14: Packaging information

Type	BOTTLE
Material:	HDPE
size:	88 mm± 4 mm/242 mm ± 6 mm
Opening:	39mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-15: Packaging information

Type	BOTTLE
Material:	HDPE
size:	238 mm± 2 mm/90mm ± 2 mm
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal

Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-16: Packaging information

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-17: Packaging information

Type	BOTTLE
Material:	HDPE
size:	84 mm± 2 mm/248.2 mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-18: Packaging information

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	cap with seal
Capacity	1200 ± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-19: Packaging information

Type	BOTTLE
Material:	HDPE
size:	84 ± 1.5 mm/230.1 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Table 4.1-20: Packaging information

Type	BOTTLE
Material:	HDPE
size:	157,2 mm± 2 mm/101mm ± 2 mm
Opening:	72 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-21: Packaging information

Type	JAR
Material:	HDPE
size:	108/110 mm/ 266 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-22: Packaging information

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-23: Packaging information

Type	BOTTLE
Material:	HDPE
size:	94 ± 1 mm/103 ± 1 mm/272.5 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-24: Packaging information

Type	BOTTLE
Material:	HDPE
size:	224,1 mm± 2 mm/122mm ± 2 mm
Opening:	73 mm ± 2 mm
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-25: Packaging information

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-26: Packaging information

Type	CANNISTER
Material:	HDPE
size:	96 ± 3 mm/195 ± 3.5 mm/297.2 ± 4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	4000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-27: Packaging information

Type	CONTAINER
Material:	HDPE
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm
Opening:	59.20 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-28: Packaging information

Type	CONTAINER
Material:	HDPE
size:	336 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-29: Packaging information

Type	CONTAINER
Material:	HDPE
size:	310,5 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-30: Packaging information

Type	CANNISTER
Material:	HDPE
size:	190 mm± 5 mm /140 mm± 5 mm/ 314 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-31: Packaging information

Type	CANNISTER
Material:	HDPE
size:	127±2 mm/192±2 mm/285±5 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-32: Packaging information

Type	CANNISTER
Material:	HDPE
size:	145±2 mm/190.8±3/294±4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	6000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-29: Packaging information for 10L container

Type	Description
Material:	HDPE
Size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	11220±50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-30: Packaging information for 10L container

Type	Description
Material:	HDPE
Size:	312 mm± 5 mm/225mm± 5 mm/185mm ± 5 mm
Opening:	40.8 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-31: Packaging information for 10L container

Type	Description
Material:	HDPE
Size:	375 mm± 5 mm/230± 5 mm/165 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml

Type	Description
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-32: Packaging information for 10L container

Type	Description
Material:	HDPE
Size:	377,7 mm± 5 mm/239,5± 5 mm/178 mm ± 5 mm
Opening:	54 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information for 10L cannister

Type	Description
Material:	HDPE
Size:	192±3 mm/228±7/313±7 mm
Opening:	52 mm ± 2 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information for 10L cannister

Type	Description
Material:	HDPE
Size:	185±2 mm/225±2/312±3 mm
Opening:	40.8 mm ± 0.3 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information for 20L container

Type	Description
Material:	HDPE
Size:	443mm/288mm/230mm
Opening:	44mm (internal) 60mm (external)
Closure:	screw cap with seal
Capacity	22000ml ± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-36: Packaging information for 20L container

Type	Description
Material:	HDPE
Size:	376.3±3 mm/295±3mm/246±3mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-38: Packaging information for 20L container

Type	Description
Material:	HDPE
Size:	376±8 mm/257,5±5/376±8 mm
Opening:	52 mm± 3
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-39: Packaging information for 20L cannister

Type	Description
Material:	HDPE
Size:	257.5±6 mm/292±8/376±8 mm ± 5 mm
Opening:	52 mm ± 2 mm

Type	Description
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information

Type	Description
Material:	HDPE
Size:	745 mm x 493 mm
Opening:	BCS 70x6/ BCS 38x6
Closure:	Bung
Capacity	124 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information

Type	Description
Material:	HDPE
Size:	90000mm/59000mm ± 2 mm
Opening:	45mm ± 2 mm
Closure:	screw cap with seal
Capacity	22000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information

Type	Description
Material:	HDPE
Size:	935 mm x 581 mm
Opening:	BCS 70x6/ BCS 56x4
Closure:	Bung
Capacity	220 L
Seal:	Induction seal
Manner of construction	extruded

Type	Description
UN/ADR	compliant

Table 4.1-37: Packaging information

Type	Description
Material:	HDPE
Size:	942 mm ± 10 mm x 582 mm ± 10 mm
Opening:	70x6 / 56 x4
Closure:	Openings on top, 3 high, straight wrapped with cover on top Bungs 70x6 and 56 x 4 lose screw
Capacity	222 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

According to guideline from Ministry of Agriculture and Rural Development (*Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin*) data of stability in the material HDPE are extrapolable to the all materials (HDPE/PA; HDPE/F; HDPE/EvOH). Therefore, no further studies are required for the additional packaging materials.

Packaging information

Packaging information for 100 ml Bottle	
Type	BOTTLE
Material:	HDPE / EVOH
Body diameter / total height:	48,50mm +- 1,00mm / 95,50mm +- 1,00mm
External thread diameter:	27,3mm +- 0,15mm
Closure:	screw cap with seal
Capacity	100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

Packaging information for 250ml BOTTLE	
Type	BOTTLE
Material:	HDPE/ EVOH
Body diameter / total height:	62,50 +- 0,50 / 126,50 +- 1,50
External thread diameter:	49,65 +- 0,35
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

500 ml pack

Material: HDPE/EvOH

Type of construction: BOTTLE

Size: 69 mm \pm 2 mm/186.5 mm \pm 2 mm

Capacity: 500 ml

Weight: 45g \pm 2 g

Type of closure: screw cap with cutter

Size of opening: 42 \pm 3 mm

500 ml pack

Material: HDPE/EvOH

Type of construction: BOTTLE

Size: 65 mm/234.8 mm \pm 2 mm

Capacity: 500 ml

Weight: 35 g \pm 2 g

Type of closure: screw cap with seal

Size of opening: 27.4 mm

1000 ml pack

Material: HDPE/EvOH

Type of construction: BOTTLE

Size: 234 \pm 3 mm/88.5 \pm 2mm

Capacity: 1000 ml

Weight: 45g \pm 2 g

Type of closure: screw cap with cutter

Size of opening: 42 mm \pm 2 mm

1000 ml pack

Material: HDPE/EvOH

Type of construction: BOTTLE

Size: 234 \pm 3 mm/88.5 \pm 2mm

Capacity: 1000 ml

Weight: 73g \pm 2 g

Type of closure: screw cap with cutter

Size of opening: 42 mm \pm 2 mm

1000 ml pack

Material: HDPE/EvOH

Type of construction: BOTTLE

Size: 234 \pm 3 mm/88.5 \pm 2mm

Capacity: 1000 ml

Weight: 73g \pm 5 g

Type of closure: screw cap with cutter

Size of opening: 50 mm \pm 3 mm

5000 ml pack

Material: HDPE/EvOH

Type of construction: CONTAINER

Size: 165 mm \pm 2 mm/195 mm \pm 2 mm/228mm \pm 2 mm

Capacity: 5000 ml

Weight: 280g ± 2 g
 Type of closure: screw cap with cutter
 Size of opening: 48 mm ± 2 mm

10 L pack
 Material: HDPE/EvOH
 Type of construction: CONTAINER
 Size: 195 mm ± 2 mm/225mm± 2 mm/306mm± 2 mm
 Capacity: 10000 ml
 Weight: 530g ± 2 g
 Type of closure: screw cap with cutter
 Size of opening: 48 mm ± 2 mm

20 L pack
 Material: HDPE/EvOH
 Type of construction: CONTAINER
 Size: 375 mm ± 2 mm/290mm± 2 mm/245mm± 2 mm
 Capacity: 10000 ml
 Weight: 1150g ± 2 g
 Type of closure: screw cap with cutter
 Size of opening: 85mm ± 2 mm

Table 4.1-1: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	62.5±1 mm/131.3±1 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	323 ± 5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	69 mm ± 2 mm/186.5 mm ± 2 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	574 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	74± 1 mm/177 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	74± 1 mm/177 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	65 mm/234.8 mm ± 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	88 mm ± 2 mm/238 mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5±3 mm/84±1.5mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5±3 mm/84±1.5mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	238± 1 mm/88 ± 1 mm/
Opening:	41.7±0,7 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-14: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	233.5± 1.5 mm/88.5 ± 1 mm/
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-15: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-16: Packaging information

Type	CONTAINER
Material:	HDPE/PA COEX
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ±5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-17: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	193 ± 3/ 142 ± 5 mm/320 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-18: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	195 ± 3/ 130 ± 5 mm/310,5 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-19: Packaging information

Type	CANNISTER
Material:	HDPE/PA COEX
size:	313± 5mm/190±3/140±5mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-20: Packaging information

Type	CONTAINER
Material:	HDPE/PA COEX
size:	305mm/193 mm/142 mm ± 5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-21: Packaging information

Type	CONTAINER
Material:	HDPE/PA COEX
size:	377,7mm/178 mm/239,5 mm ± 5 mm
Opening:	54 mm min ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-24: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	50 ± 1 mm/93 ± 1 mm
Opening:	28,4 ± 0,3 mm
Closure:	screw cap with seal
Capacity	120 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-25: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	63.5±1 mm/126±1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	318 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-26: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	63.5±1 mm/126±1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	312 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-27: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	585 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-28: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	580 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-29: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	575 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-30: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	570 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-31: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1150 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-32: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1160 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1170 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1185 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1200 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-36: Packaging information

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-37: Packaging information

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-38: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	54,2 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-39: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	63.4 mm min ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-40: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	67,5 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-41: Packaging information

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	54,2 mm min ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-42: Packaging information

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	63,4 mm min ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-43: Packaging information

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	67,5 mm min ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-44: Packaging information

Type	Cannister
Material:	HDPE/F
size:	240±2 mm/179±2mm/375±3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	10 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

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 2.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.7.5 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.3 KCP 2.8.5.1.1 KCP 2.8.5.1.2. KCP 2.8.7.2	Al Amin, I.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code no. BF-07/18 Institute of Industrial Organic Chemistry, Warsaw, Poland GLP Unpublished	N	Letter of access from: Synthos Agro

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 2.8.2					
KCP 2.1 KCP 2.4.2 KCP 2.7.3 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.3 KCP 2.8.5.1.1 KCP 2.8.5.1.2. KCP 2.8.7.2 KCP 2.11	Al Amin, I.	2019	Terbut 500 SC Part II: Determination of physicochemical properties after the first year storage Study code no. BF-07/18 Institute of Industrial Organic Chemistry, Warsaw, Poland GLP Unpublished	N	Letter of access from Synthos Agro
KCP 2.2.1	Śliwa, P.	2018	Terbut 500 SC Determination of explosive properties Study code: BW-14/18 Institute of Industrial Organic Chemistry, Warsaw, Poland GLP Unpublished	N	Letter of access from Synthos Agro
KCP 2.3.1 KCP 2.3.3	Flasińska, P.	2018	Terbut 500 SC Determination of flash point and auto-ignition temperature Study No.: BC-31/18 Institute of Industrial Organic Chemistry, Warsaw, Poland GLP Unpublished	N	Letter of access from Synthos Agro
KCP 2.1 KCP 2.4.2 KCP 2.7.3 KCP 2.8.2	E. Arevalo	2020	Terbut 500 SC Part III: Determination of physicochemical properties after the second year of storage Study No.: BF-07/18 Łukasiewicz Instytut Przemysłu Organicznego, Warsaw, Poland GLP	N	Letter of access from Synthos Agro

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 2.8.3.1 KCP 2.8.3.3 KCP 2.8.5.1.1 KCP 2.8.5.1.2. KCP 2.8.7.2 KCP 2.11			unpublished		
KCP 2.4.2 KCP 2.7.1 KCP 2.7.3 KCP 2.7.5 KCP 2.8.2 KCP 2.8.3.1 KCP 2.11	E. Arevalo	2020	TERBUT 500 SC Determination of physicochemical properties of the initial preparation and after accelerated storage Study code: BF-07/20 Łukasiewicz Instytut Przemysłu Organicznego, Warsaw, Poland GLP unpublished	N	Chemirol Sp. z o.o.
KCP 2.9.1	I. Knapik	2020	Determination of physicochemical properties Study code: ICB/119/2020 ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.7.4	J. Zieliński	2021	TERBUT 500 SC - Determination of dispersion spontaneity of the preparation after low temperature storage Study code FB-49/21 Łukasiewicz Instytut Przemysłu Organicznego, Warsaw, Poland 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 Published or not	Vertebrate study Y/N	Owner

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

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

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

Not required