

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 names: **TERBUT 500 SC/
TAZOPRYM 500SC / CORNAO 500 SC**

Chemical active substance:

Terbuthylazine, 500 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

Finalisation date: 08.2021; 03.2022, 06.2022

Version history

When	What
August 2021	Assessment by the experts
March 2022	Final Registration Report
June 2022	Update according to Reg. 2021/824 , 21.05.2021 r.

Table of Contents

1	Section 1: Identity of the plant protection product.....	4
1.1	Applicant (KCP 1.1)	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2)	4
1.2.1	Producer(s) of the preparation	4
1.2.2	Producer(s) of the active substance(s)	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s)	4
1.2.3.1	Terbuthylazine	4
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3)	4
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)	5
1.4.1	Composition of the plant protection product (KCP 1.4.1)	5
1.4.2	Information on the active substance(s) (KCP 1.4.2)	6
1.5	Type and code of the plant protection product (KCP 1.5)	6
1.6	Function (KCP 1.6)	6
2	Section 2: Physical, chemical and technical properties of the plant protection product	7
3	Section 3 is presented as a separate document	19
4	Section 4: Further information on the plant protection product	20
4.1	Packaging and Compatibility with the Preparation (KCP 4.4)	20
Appendix 1	Lists of data considered in support of the evaluation	22
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance.....	28
A 2.1	Terbuthylazine	28

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Synthos Agro Sp. z o.o.
Address: ul. Chemików 1
32-600 Oświęcim
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 Terbuthylazine

Terbuthylazine min. 950 g/kg

Propazine max. 9 g/kg*

Atrazine max. 1 g/kg

Simazine max. 9 g/kg*

* Update according to Reg. 2021/824 ,21.05.2021.

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: TERBUT 500 SC
TAZOPRYM 500 SC
CORNAO 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)
Terbuthylazine	500 g/kg	± 20 g/kg	526.3 g/kg	46.8 %w/w

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

** Based on the density of the formulation = 1.125 g/ml.

Table 1.4-2: Safener and synergists

Neither safener nor synergists were used in the formulation.

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Propazine	<p>max. 10 9 g/kg* g/kg in the active substance as manufactured (g/kg)</p> <p>max 5.3 4.7 g/l of TERBUT 500 SC here in TERBUT 500 SC the results is <LOQ (0,0004% = 4ppm)</p> <p>* Update according to Reg. 2021/824 21.05.2021.</p>
Atrazine	<p>max. 1 g/kg in the active substance as manufactured (g/kg)</p> <p>max 0.5 g/L of TERBUT 500 SC here in TERBUT 500 SC the results is <LOQ (0,0002% = 2ppm)</p>
Simazine	<p>max. 30 9 g/kg* g/kg in the active substance as manufactured (g/kg)</p> <p>max 15.8 4.7 g/L of TERBUT 500 SC here in TERBUT 500 SC the results is 0.0009 % = 0.0387g/L)</p> <p>* Update according to Reg. 2021/824 21.05.2021</p>

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

Table 1.4-4: Information on Terbutylazine

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

Table 1.4-5: 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: SC (Suspension Concentrate)

[Code: TERBUT 500 SC]

1.6 Function (KCP 1.6)

Herbicide

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogenous white liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point up to the boiling point. It has a self ignition temperature above 650 °C. 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 *Suspension Concentrate* formulation.

The intended concentration of use is 0.33% to 0.50%.

Physical-Chemistry data cover concentration from 0.27% to 0.75%.

All results are within the scope of acceptance.

Due to the fact that those concentration uses represents worse case than intended they should be deemed as accepted.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only: none

Classification

Accute Tox.4	H302: Harmful if swallowed
Skin Sens. 1	H317: May cause an allergic skin reaction
STOT RE 2	H373: May cause damage to organs through prolonged or repeated exposure
Aquatic Acute 1	H400: Very toxic to aquatic life
Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects

Labelling

Pictograms:

GHS 07 – Exclamation mark
GHS 08 – Health hazard
GHS 09 - Environment

Signal words:

Warning

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Hazard Statements:

H302: Harmful if swallowed
H317: May cause an allergic skin reaction
H410: Very toxic to aquatic life with long lasting effects
H373: May cause damage to organs through prolonged or repeated exposure

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary Statements:

Prevention:

- P260 – Do not breathe dust/fumes/gas/mist/vapours/spray.
- P261 - Avoid breathing dust/fume/ gas/mist/vapours/spray.
- P264 – Wash hands thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P272 - Contaminated work clothing should not be allowed out of the workplace.
- P273 - Avoid release to the environment.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection.

Response:

- P314 - Get medical advice/attention if you feel unwell.
- P321 - Specific treatment (see on this label).
- P302 + P352 - IF ON SKIN: Wash with plenty of water.
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/ attention.
- P362 + P364 - Take off contaminated clothing and wash it before reuse.
- P330 - Rinse mouth.
- P391 - Collect spillage.

Disposal:

- P501 - Dispose of contents/container to an approved waste disposal plant.

Compliance with FAO specifications:

FAO Specification 234/SC/S for Terbutylazine Suspension Concentrate

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Organoleptic	Terbut 500 SC Batch No.: 1/2018	Homogenous white liquid of characteristic odour	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	Terbut 500 SC Batch No.: 1/2018	Terbut 500 SC does not have explosive properties according to the criteria of EEC A.14 method.	Y	Paweł Śliwa, MSc.; Institute of Industrial Organic Chemistry; BW-14/18; Warsaw; March 2018	Accepted
Oxidizing properties (KCP 2.2.2)			Not applicable. Considering the composition of the formulation and the individuals components, the product is not expected to have oxidizing properties.			Statement accepted
Flash point (KCP 2.3.1)	EEC A.9.	Terbut 500 SC Batch No.: 1/2018	The product has not got the flash point up to the boiling point according to A.9 method.	Y	Paulina Flasińska, MSc.; Institute of Industrial Organic Chemistry; BC-31/18; Warsaw; March 2018	Accepted
Flammability (KCP 2.3.2)			Not applicable. It is not a solid or gas plant protection product.			Statement accepted
Self-heating (KCP 2.3.3)	EEC A.15.	Terbut 500 SC Batch No.: 1/2018	The product has not got the auto-ignition temperature up to 650 °C according to A.15 method.	Y	Paulina Flasińska, MSc.; Institute of Industrial Organic Chemistry; BC-31/18; Warsaw; March 2018	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Acidity or alkalinity and pH (KCP 2.4.1)			Not applicable. It is not a plant protection product which is acidic (pH < 4) or alkaline (pH > 10).			Statement accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Terbut 500 SC Batch No.: 1/2018	7.76	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Viscosity (KCP 2.5.1)	OECD 114	Terbut 500 SC Batch No.: 1/2018	Dynamic: at 20°C: at shear rate of 2.5 s ⁻¹ 1875 mPa·s, at shear rate of 5 s ⁻¹ 1112 mPa·s, at shear rate of 10 s ⁻¹ 668 mPa·s, at shear rate of 25 s ⁻¹ 354 mPa·s, at 40°C: at shear rate of 2.5 s ⁻¹ 1603 mPa·s, at shear rate of 5 s ⁻¹ 950 mPa·s, at shear rate of 10 s ⁻¹ 563 mPa·s, at shear rate of 25 s ⁻¹ 292 mPa·s.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted RMS Comments: Kinetic viscosity: at 20°C: at shear rate of 2.5 s ⁻¹ 1741mm ² /s, at shear rate of 5 s ⁻¹ 1011mm ² /s, at shear rate of 10 s ⁻¹ 607mm ² /s, at shear rate of 25 s ⁻¹ 322 mm ² /s, at 40°C: at shear rate of 2.5 s ⁻¹ 1457 mm ² /s, at shear rate of 5 s ⁻¹ 864 mm ² /s, at shear rate of 10 s ⁻¹ 512 mm ² /s, at shear rate of 25 s ⁻¹ 265 mm ² /s,
Surface tension (KCP 2.5.2)	EEC A.5	Terbut 500 SC	43.23 mN/m	Y	Idris Al Amin, Ph.D.; Institute of Industrial	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No.: 1/2018			Organic Chemistry; BF-07/18; Warsaw; March 2018	
Density (KCP 2.6.1)	CIPAC MT 3.2	Terbut 500 SC Batch No.: 1/2018	At 20°C: absolute 1.105 g/ml, relative 1.105 g/ml, At 40°C: absolute 1.097 g/ml, relative 1.097 g/ml.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Bulk density (KCP 2.6.2)			Not applicable. It is not a plant protection product in the form of powder or granules.			Statement accepted
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Terbut 500 SC Batch No.: 1/2018		Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted RMS Comments: Active substance content and stability of packaging were tested. All physical and chemical properties remained stable after the test and accepted. Test carried out in HDPE bottles.
	Organoleptic		Homogenous white liquid of characteristic odour			
	CIPAC MT 75.3		pH Determination of 1%: 7.49			
	CIPAC MT 184		Suspension stability: At concentration 0.8 l in 300 l: 101.58% At concentration 1.5 l in 200 l: 100.69%			
	CIPAC MT 160		Dispersion spontaneity: 94.33%			
	CPAC MT 185		Wet sieve test: 0.75 %			
	CIPAC MT 148.1		Pourability:			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			R = 4.22%, R' = 0.35%			
	CIPAC MT 187		Particle size distribution: d ₁₀ = 0.64 µm, d ₅₀ = 2.24 µm d ₉₀ = 5.92 µm, d _{4,3} = 2.82 µm SD = 0.029 µm, RSD = 1.021%.			
	HPLC		Active substance content: Terbutylazine : 46.83% (517.47 g/l) Relevant impurities content: Atrazine: <LOQ Propazine: <LOQ Simazine: 0.038% (0.4169 g/l)			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			Not applicable. The product is chemically and physically stable after storage for 14 days at 54° C.			Statement accepted
Minimum content after heat stability testing (KCP 2.7.3)	CIPAC MT 46 (HPLC)	Terbut 500 SC Batch No.: 1/2018	Terbutylazine : 46.83% (517.47 g/l)	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.1	Terbut 500 SC Batch No.:	Homogenous white liquid of characteristic odour	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry;	Accepted RMS Comments: The product is stable in
	CPAC MT 185		Wet sieve test: 0.00% residue in 75 µm sieve			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 184	1/2018	Suspension stability: At concentration 0.8 l in 300 l: 101.22% At concentration 1.5 l in 200 l: 100.71%		BF-07/18; Warsaw; March 2018	low temperature study.
Ambient temperature shelf life (KCP 2.7.5)	Visual inspection	Terbut 500 SC Batch No.: 1/2018	<u>After the first year:</u> Homogenous white liquid of characteristic odour <u>After the second year:</u> Homogenous white liquid of characteristic odour	Y	Enzo Arévalo, Ph.D.; Research Network Łukasiewicz Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; 2020	Accepted RMS Comments: Active substance content and stability of packaging were tested. All physical and chemical properties remained stable after the test and accepted. Based on 2-years storage stability study: - shelf life is: 2 years Test carried out in HDPE bottles.
	HPLC		<u>After the first year:</u> Active substance content: Terbuthylazine 46.52% (514.1 g/l) Relevant impurities contents: Atrazine < LOQ Propazine 0.0045% (0.049 g/l) Simazine 0.045% (0.497 g/l) <u>After the second year:</u> Active substance content: Terbuthylazine 46.79% (517.1 g/l) Relevant impurities contents: Atrazine < LOQ Propazine < LOQ Simazine 0.035% (0.387 g/l)			
	CIPAC MT 75.2		<u>After the first year:</u> pH Determination of 1%: 7.46 <u>After the second year:</u>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			pH Determination of 1%: 7.60 pH undiluted: 7.14			
	CIPAC MT 160		<u>After the first year:</u> Dispersion spontaneity: 87.21% <u>After the second year:</u> Dispersion spontaneity: 90.17%			
	CIPAC MT 184		<u>After the first year:</u> Suspension stability: At concentration 0.27%: 99.46% At concentration 0.75%: 100.28% <u>After the second year:</u> Suspension stability: At concentration 0.27%: 100.62% At concentration 0.75%: 100.07% At concentration 0.2%: 99.69%			
	CPAC MT 185		<u>After the first year:</u> Wet sieve test: 0.00% <u>After the second year:</u> Wet sieve test:			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			0.00%			
	CIPAC MT 148.1		<u>After the first year:</u> Pourability: R = 3.60% R' = 0.24% <u>After the second year:</u> Pourability: R = 3.17% R' = 0.37%			
	CIPAC MT 187		<u>After the first year:</u> Particle size distribution: d10 = 0.56 µm d50 = 1.94 µm d90 = 5.39 µm d4,3 = 2.51 µm SD = 0,044 µm RSD = 1.75% <u>After the second year:</u> Particle size distribution: d10 = 0.608µm d50 = 2.107 µm d90 = 5.758 µm d4,3 = 2.719 µm SD = 0,011 µm RSD = 0.42%			
	GIFAP No.17		<u>After the first year:</u> Package evaluation: Stable, white cylindrical HDPE bottles <u>After the first year:</u>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Package evaluation: Stable, white cylindrical HDPE bottles			
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not applicable. Proposed shelf life is not less than 2 years.			Statement accepted
Wettability (KCP 2.8.1)			Not applicable. It is not a solid plant protection product, which is diluted for use.			Statement accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Terbut 500 SC Batch No.: 1/2018	Concentration 1.5 l in 200 l: after 1 min - 10 ml, after 12 min - 7 ml.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Terbut 500 SC Batch No.: 1/2018	Suspension stability: At concentration 0.8 l in 300 l: 100.31% At concentration 1.5 l in 200 l: 99.61%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Terbut 500 SC Batch No.: 1/2018	Dispersion spontaneity: 84.57%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Dispersion stability (KCP 2.8.3.3)			Not applicable. It is not a water dispersible plant protection product.			Statement accepted
Degree of dissolution and dilution stability (KCP 2.8.4)			Not applicable. It is not a water soluble plant protection product.			Statement accepted

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.: 1/2018	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%.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CPAC MT 185	Terbut 500 SC Batch No.: 1/2018	0.00 %	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted
Dust content (KCP 2.8.5.2.1)			Not applicable. It is not a granular plant protection product.			Statement accepted
Particle size of dust (KCP 2.8.5.2.2)			Not applicable. It is not a granular plant protection product.			Statement accepted
Attrition (KCP 2.8.5.3)			Not applicable. It is not a plant protection product in the form of granules or tablets which are loose packed.			Statement accepted
Hardness and integrity (KCP 2.8.5.4)			Not applicable. It is not a plant protection product in the form of tablets.			Statement accepted
Emulsifiability (KCP 2.8.6.1)			Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.			Statement accepted
Emulsion stability (KCP 2.8.6.2)			Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.			Statement accepted
Re-emulsifiability (KCP 2.8.6.3)			Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.			Statement accepted
Flowability			Not applicable.			Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.7.1)			It is not a granular plant protection product.			
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Terbut 500 SC Batch No.: 1/2018	Pourability: R = 5.53%, R' = 0.39%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/18; Warsaw; March 2018	Accepted RMS Comments: As the results are slightly outside the acceptable range, it is recommended to rinse the spray tank three times.
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable. It is not a plant protection product in the form of dustable powder.			Statement accepted
Physical compatibility of tank mixes (KCP 2.9.1)			Not applicable. No tank mixtures with this product are recommended.			Statement accepted
Chemical compatibility of tank mixes (KCP 2.9.2)			Not applicable. No tank mixtures with this product are recommended.			Statement accepted
Adhesion to seeds (KCP 2.10.1)			Not applicable. It is not a plant protection product for seed treatment.			Statement accepted
Distribution to seed (KCP 2.10.2)			Not applicable. It is not a plant protection product for seed treatment.			Statement accepted
Other/special studies (KCP 2.11)	According to brochure “Dobra praktyka postępowania przy stosowaniu środków ochrony roślin” issued by Research Institute of Horticulture (Instytut Ogrodnictwa, Skierniewice 2014,	Terbut 500 SC Batch No.: 7/2017	Residues of Terbutylazine in the tank after the cleaning procedure corresponded to <0.05% of the initial concentration in spray liquid. Considering the results, cleaning of the spray equipment with water is considered adequate and no adverse effect would be expected.	N	Piotr Paleń; Synthos Agro Sp. z o.o.; AGRO/17/18; Oświęcim; March 2018	Accepted

Annex point	Method used / deviations	Test ma- terial	Findings	GLP Y/N	Reference	Acceptability / comments
	ISBN 978-83-89800-63-3)					

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)

Terbut 500 SC is packaged in the following way:

HDPE Bottles and canisters 1L, 5L, 10L, 20L.

RMS Comments:

Recommended packaging are accepted (HDPE Bottles 1L and canisters 5L, 10L, 20L)

Table 4.1-1: Packaging information for 1 litre bottle

Type	Description
Trade name:	Romak – Butelka D7 z wlewem Φ 40
Material:	HDPE
Shape/size:	cylindrical / approx. 88.5 ± 1 mm diameter x 231 ± 2 mm; weight 78 ± 2 g
Opening:	40 ± 1 mm inner diameter

Table 4.1-2: Packaging information for 1 litre bottle

Type	Description
Trade name:	Suwary – Butelka BO-1
Material:	HDPE
Shape/size:	cylindrical / approx. 84 ± 1.5 mm diameter x 230.1 ± 3 mm
Opening:	38 mm outer diameter

Table 4.1-3: Packaging information for 1 litre bottle

Type	Description
Trade name:	Romak – Butelka D7 z wlewem Φ 55
Material:	HDPE
Shape/size:	cylindrical / approx. 88.5 mm diameter x 227 mm; weight 80 ± 2 g
Opening:	55 mm inner diameter

Table 4.1-2: Packaging information for 5 litre bottle canister

Type	Description
Trade name:	Romak - Kanister “AGRO”
Material:	HDPE
Shape/size:	canister / approx. 195 mm x 139 mm x 305 mm; weight 230 g

Type	Description
Trade name:	Romak - Kanister "AGRO"
Opening:	39 mm inner diameter

Table 4.1-2: Packaging information for 10 litre bottle canister

Type	Description
Trade name:	Romak – Kanister K8 z wlewem Φ 40
Material:	HDPE
Shape/size:	canister / approx. 222 ± 3 mm x 182 ± 3 mm x 323 ± 5 mm
Opening:	40 ± 1 mm inner diameter

Table 4.1-2: Packaging information for 10 litre bottle canister

Type	Description
Trade name:	Suwary – Kanister K-10N
Material:	HDPE
Shape/size:	canister / approx. 228 ± 7 mm x 192 ± 3 mm x 313 ± 7 mm
Opening:	52 mm outer diameter

Table 4.1-2: Packaging information for 20 litre bottle canister

Type	Description
Trade name:	Suwary – K-20N
Material:	HDPE
Shape/size:	canister / approx. 292 ± 8 mm x 257.5 ± 6 mm x 376 ± 8 mm
Opening:	52 mm inner diameter

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.2.1	Paweł Śliwa, M. Sc.	2018	Terbut 500 SC Determination of explosive properties. Institute of Industrial Organic Chemistry; BF-14/18; Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.3.1	Paulina Flasińska, MSc.	2018	Terbut 500 SC Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry BC-31/18; Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.3.3	Paulina Flasińska, MSc.	2018	Terbut 500 SC Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry	N	Synthos Agro Sp. z o.o.

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
			BC-31/18; Warsaw; March 2018 GLP Unpublished		
KCP 2.4.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.5.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.5.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.6.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation,	N	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
			after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished		Sp. z o.o.
KCP 2.7.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.3	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.4	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.

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 2.7.5	Enzo Arévalo, Ph.D.;	2020	Terbut 500 SC Part II: Determination of physicochemical properties after the second year storage. Research Network Łukasiewicz Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2020 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.3.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.3.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 2.8.5.1.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.5.1.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.7.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.11	Piotr Paleń, M. Sc.	2018	Terbut 500 SC Effectiveness of the equipment cleaning procedure Piotr Paleń Synthos Agro Sp. z o.o.; AGRO/17/18; Oświęcim;	N	Synthos Agro Sp. z o.o.

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
			March 2018 Non GLP Unpublished		

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

A 2.1 Terbuthylazine

No new or additional data.