

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: H-01-2022

Product name(s): Terbutylazyna 500 SC

Chemical active substance:

terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: ProAgri International Sp. z o.o.

Submission date: April 2024

MS Finalisation date: 01.2025; 03.2025

Version history

When	What
04.2024	Submission date
01.2025	zRMS first evaluation
03.2025	The final Registration Report

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zRMS comment:

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

Data gap – shelf life study, estimated completion date – February/March 2025. Based on the formulation composition and accelerated storage results, a 2-year provisional authorisation is possible and proposed.

Commercial packaging: f-HDPE; acceptable based on the accelerated storage study.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: ProAgri International Sp. z o.o.
Address: ul. Józefa Piusa Dziekońskiego 1
00-728 Warszawa
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 ≥ 950 g/kg (Reg. (EU) 2021/824)
min 980 g/kg (ProAgri source)

Relevant impurity	Maximum content (g/L or g/kg)
Propazine	maximum of 9 g/kg (Reg. (EU) 2021/824)
Atrazine	maximum of 1 g/kg (Reg. (EU) 2021/824)
Simazine	maximum of 9 g/kg (Reg. (EU) 2021/824)

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

Trade name: Please refer to application form

Company code number: H-01-2022

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/L	475 – 525 g/L	CONFIDENTIAL information provided separately (Part C). 510.2	45.59

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

** Based on the density of the formulation = 1.119 g/mL

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Propazine	maximum of 9 g/kg (Reg. (EU) 2021/824) max 4.59 g/L
Atrazine	maximum of 1 g/kg (Reg. (EU) 2021/824) max 0.59 g/L
Simazine	maximum of 9 g/kg (Reg. (EU) 2021/824) max 4.59 g/L

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

Table 1.4-4: Information on terbuthylazine

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

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

Not relevant. Product does not contain safeners and synergists.

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

Type: Suspension concentrate

[Code: 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 homogenous whitish liquid of characteristic odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 445°C. In aqueous 1% solution, it has a pH value around 6.05 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. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.33 – 0.67%.

The product is not intended to be used in tank mixtures.

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

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

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not relevant.

Compliance with FAO specifications:

The product H-01-2022 complies with FAO specifications.

Formulation used for tests

Product used in the test 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)	Visual assessment	H-01-2022 Batch no. 1/23	White suspension, no separation phase, homogeneous, plastic odour, whitish colour.	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted
Explosive properties (KCP 2.2.1)	Justification	-	It is proposed that product H-01-2022 will not exhibit explosive properties as neither the active ingredient nor the co-formulants demonstrate explosive properties according to their respective Safety Data Sheets (SDSs).	-	-	Accepted The absence of explosive properties of formulation has been based on SDS of the active ingredient and co-formulants. Explosive properties are not expected
Oxidizing properties (KCP 2.2.2)	Justification	-	It is proposed that product H-01-2022 will not exhibit oxidising properties as neither the active ingredient nor the co-formulants demonstrate oxidising properties according to their respective SDSs.	-	-	Accepted The absence of explosive properties of formulation has been based on SDS of the active ingredient and co-formulants. Oxidizing properties are not expected
Flash point	A.9	H-01-2022	No ignition.	Y	Condorelli	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.3.1)		Batch no. 1/23	80°C: vapours turn off the flame.		A.M.M., 2023; Report No. 22363-02C	Considered not flammable
Flammability (KCP 2.3.2)	-	-	Not relevant. H-012022 is liquid form.	-	-	-
Self-heating (KCP 2.3.3)	A.15	H-01-2022 Batch no. 1/23	H-01-2022 has got the auto-ignition temperature: 445°C.	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted Considered not auto-flammable
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	H-01-2022 Batch no. 1/23	<u>Before storage:</u> pH (Neat) = 7.40 at app. 24 °C <u>After accelerated storage:</u> pH (Neat) = 7.15 at app. 24 °C	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted Based on the results, acidity or alkalinity test not required
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	H-01-2022 Batch no. 1/23	<u>Before storage:</u> pH (1%) = 6.05 at 20 °C <u>After accelerated storage:</u> pH (1%) = 5.85	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted Based on the results, acidity or alkalinity test not required
Viscosity (KCP 2.5.1)	OECD 114	H-01-2022 Batch no. 1/23	Result of viscosity determination at 20°C	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted The formulation has a non-newtonian behaviour. Aspiration hazard is not expected, the formulation does not have to be

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																																																			
			<table><tr><td>Spindle</td><td>Speed</td><td>Viscosity</td></tr><tr><td>[-]</td><td>[rpm]</td><td>[mPa s]</td></tr><tr><td rowspan="4">RH7</td><td>3</td><td>4000.0</td></tr><tr><td>9.65</td><td>1658.0</td></tr><tr><td>31.1</td><td>643.0</td></tr><tr><td>100</td><td>279.9</td></tr><tr><td rowspan="4">RH6</td><td>3</td><td>3000.0</td></tr><tr><td>9.65</td><td>1347.0</td></tr><tr><td>31.1</td><td>546.6</td></tr><tr><td>100</td><td>239.9</td></tr><tr><td rowspan="4">RH5</td><td>3</td><td>2800.0</td></tr><tr><td>9.65</td><td>1161.0</td></tr><tr><td>31.1</td><td>488.7</td></tr><tr><td>100</td><td>227.9</td></tr><tr><td rowspan="4">RH4</td><td>3</td><td>2733.0</td></tr><tr><td>9.65</td><td>1119.0</td></tr><tr><td>31.1</td><td>469.4</td></tr><tr><td>100</td><td>225.9</td></tr><tr><td rowspan="4">RH3</td><td>3</td><td>2600.0</td></tr><tr><td>9.65</td><td>1047.0</td></tr><tr><td>31.1</td><td>453.3</td></tr><tr><td>100</td><td>213.9</td></tr></table>			Spindle	Speed	Viscosity	[-]	[rpm]	[mPa s]	RH7	3	4000.0	9.65	1658.0	31.1	643.0	100	279.9	RH6	3	3000.0	9.65	1347.0	31.1	546.6	100	239.9	RH5	3	2800.0	9.65	1161.0	31.1	488.7	100	227.9	RH4	3	2733.0	9.65	1119.0	31.1	469.4	100	225.9	RH3	3	2600.0	9.65	1047.0	31.1	453.3	100	213.9			classified as Asp. Tox 1.
Spindle	Speed	Viscosity																																																									
[-]	[rpm]	[mPa s]																																																									
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			Result of viscosity determination at 40°C																																																								

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Spindle	Speed	Viscosity			
			[-]	[rpm]	[mPa s]			
			RH7	3	5333.0			
				9.65	2073.0			
				31.1	643.0			
				100	279.9			
			RH6	3	3333.0			
				9.65	1244.0			
				31.1	514.4			
				100	219.9			
			RH5	3	2800.0			
				9.65	1119.0			
				31.1	463.0			
				100	211.9			
			RH4	3	2600.0			
				9.65	1057.0			
				31.1	450.0			
				100	201.9			
			RH3	3	2600.0			
				9.65	1016.0			
31.1	424.4							
100	191.9							
Surface tension (KCP 2.5.2)	A.5 OECD 115	H-01-2022 Batch no. 1/23	1.5%: 43.12 mN/m neat: 33.21 mN/m at 20°C (±0.5 °C)			Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted Tested at a conc. higher than the highest in use concentration (0.67%). Considered surface active.
Relative density	A.3	H-01-2022	Density: 1.119 g/ml at 20 °C			Y	Condorelli	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments			
(KCP 2.6.1)	OECD 109	Batch no. 1/23	Relative density: 1.119		A.M.M., 2023; Report No. 22363-02C				
Bulk density (KCP 2.6.2)	-	-	Not relevant. H-01-2022 is liquid form.	-	-	-			
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4 Visual assessment CIPAC 75.3 CIPAC 47.3 CIPAC 184 CIPAC 160 CIPAC 185 CIPAC 148 HPLC-DAD	H-01-2022 Batch no. 1/23	Storage stability after 14 days at 54°C		Y	Condorelli A.M.M., 2023; Report No. 22363-02C Condorelli A.M.M., 2025; Report No. 22363-02C (Amendment No. 1)	Accepted Stored in a commercial packaging (f-HDPE bottle). The HPLC-DAD methods for a.s. and impurities have been validated according to SANCO/3030/99 rev.5, see Part B5 for details. A.s. decrease after storage: app. 3%. Relevant impurities content < max permitted level. No significant changes in the physical, chemical or technical properties of the formulation after storage. As the formulation		
			Test type					Initial preparation	After accelerated storage
			Appearance					White suspension, no separation phase, homogeneous, plastic odour, whitish colour	White suspension, no separation phase, homogeneous, plastic odour, whitish colour
			pH	undiluted				7.40	7.15
				1% dilution				6.05	5.85
			Persistent foam					1.5%: After 1'=44.4 mL 1.5%: After 12'=24.4 mL 1%: After 1'=21.3 mL 1%: After 12'=11.3 mL	1.5%: After 1'=22.0 mL 1.5%: After 12'=11.9 mL 1%: After 1'=11.3 mL 1%: After 12'=5.6 mL
			Suspensibility					0.25%: 100% 1.5%: 100%	0.25%: 99% 1.5%: 101%
			Dispersion spontaneity					100%	100%
			Wet sieve (residue in 75 µm)					0.03%	0.30%
			Pourability					R = 2.90%	R = 2.66%
			Package stability					f-HDPE bottle, intact, no leaks	Unchanged Weight change: -0.65g
			Active substance content					44.8% w/w 501 g/L	43.4% w/w 486 g/L
			Relevant impurity content					Atrazine: below LOQ ³ Propazine: below LOQ ⁴ Simazine: 0.336 g/kg of AI ²	Atrazine: below LOQ ³ Propazine: below LOQ ⁴ Simazine: 0.446 g/kg of AI ²

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				(0.177 g/L of Test Item) ¹	(0.233 g/L of Test Item) ¹			contains an antifoaming agent, the lowest recommended conc. should be tested. However, as the results at 1% are: - initial - 21.3 mL of foam after 1min - after storage - 11.3 mL of foam after 1 min, it is unlikely that the foam volume at 0.33% would exceed the maximum allowable limit of 60 mL.
			¹ Referred to nominal test item solution concentration of 30 mg/mL, Density of test item of 1.119 g/mL ² Referred to %purity of technical material of 95%, Content of AI % of 44.76% w/w. ³ 0.5099 g/kg of AI1 0.2688 g/L of Test Item ² ⁴ 1.3436 g/kg of AI1 0.7084 g/L of Test Item ²					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant. H-01-2022 was stable after 14 days at 54°C.			-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	Internal method validated in study 22363-01C	H-01-2022 Batch no. 1/23	Before storage: 44.8% w/w (501 g/L) After storage: 43.4% w/w (486 g/L) The active substance content has not decreased by more than 5% of the initial content after the heat stability test.			Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted A.s. decrease after accelerated storage: 3.125%
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	H-01-2022 Batch no. 1/23	Storage stability after 7 days at 0°C			Y	Condorelli A.M.M., 2023; Report No. 22363-	Accepted Regarding the suspensibility
			Test type	Initial preparation	After accelerated storage			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Appearance	White suspension, no separation phase, homogenous, plastic odour, whitish colour	White suspension, no separation phase, homogeneous, plastic odour, whitish colour		02C	study, the concentrations tested were lower and higher than the lowest and the highest recommended conc. (0.33 – 0.67%).
			Suspensibility	0.25%: 100% 1.5%: 100%	0.25%: 99% 1.5%: 100%			
			Dispersion spontaneity	100%	101%			
			Wet sieve (residue in 75 µm)	0.03%	0.03%			
								Not affected by low temperature
Ambient temperature shelf life (KCP 2.7.5)	-	-	Study will be provided as available.			-	-	Data gap Approximate completion date – February/March 2025. Based on the formulation composition and accelerated storage results, a 2-year provisional authorisation is possible and proposed.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant.			-	-	-
Wettability (KCP 2.8.1)	-	-	Not relevant. H-01-2022 is liquid form.			-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	H-01-2022 Batch no. 1/23	1.5%: After 1’= 44.4 mL 1.5%: After 12’= 24.4 mL 1%: After 1’= 21.3 mL			Y	Condorelli A.M.M., 2023; Report	Accepted As the formulation contains an

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			1%: After 12'= 11.3 mL				No. 22363-02C	antifoaming agent, the lowest recommended conc. should be tested. However, as the results at 1% are: - initial - 21.3 mL of foam after 1min - after storage - 11.3 mL of foam after 1 min, it is unlikely that the foam volume at 0.33% would exceed the maximum allowable limit of 60 mL.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	H-01-2022 Batch no. 1/23				Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted The concentrations tested were lower and higher than the lowest and the highest recommended conc. (0.33 – 0.67%).
			Concentration	Initial preparation	After accelerated storage			
			0.25%	100%	99%			
			1.5%	100%	101%			
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	H-01-2022 Batch no. 1/23	<u>Before storage:</u> 100%; <u>After accelerated storage:</u> 100%.			Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted
Dispersion stability	-	-	Not required for SC formulation.			-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.3)						
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for SC formulation.	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	H-01-2022 Batch no. 1/23	Dv(10) (µm): 1.208 Dv(50) (µm): 2.036 Dv(90) (µm): 3.332 D[4][3] (µm): 2.177 %V < 50µ (%) 100	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	H-01-2022 Batch no. 1/23	Residue on 75 µm sieve: <u>Before storage:</u> 0.03 %; <u>After accelerated storage:</u> 0.30 %.	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant. H-01-2022 is liquid form.	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant. H-01-2022 is liquid form.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not relevant. H-01-2022 is liquid form.	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant. H-01-2022 is liquid form.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for SC formulation.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant. H-01-2022 is a suspension concentrate.	-	-	-
Re-emulsifiability	-	-	Not relevant. H-01-2022 is a suspension concentrate.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.6.3)						
Flowability (KCP 2.8.7.1)	-	-	Not relevant. H-01-2022 is a suspension concentrate.	-	-	-
Pourability (KCP 2.8.7.2)	CIPAC MT 148	H-01-2022 Batch no. 1/23	Before storage: R = 2.90%; After accelerated storage: R = 2.66%.	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant. H-01-2022 is liquid form.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant. H-01-2022 is not recommended for tank-mixes usage.	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant. H-01-2022 is not recommended for tank-mixes usage.	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant. H-01-2022 is not a seedtreatment.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not relevant. H-01-2022 is not a seedtreatment.	-	-	-
Other/special studies (KCP 2.11)	PSD 305 EPPO PP 1/292	H-01-2022 Batch no. 1/23	Cleaning procedure: 0.65% residue after last wash	Y	Condorelli A.M.M., 2023; Report No. 22363-02C	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
			<table><tr><th rowspan="2">Wash No.</th><th colspan="2">Residue</th></tr><tr><th>[mg]</th><th>[%]</th></tr><tr><td>Initial</td><td>369.10</td><td>54.77</td></tr><tr><td>first wash</td><td>3.68</td><td>0.55</td></tr><tr><td>second wash</td><td>2.82</td><td>0.42</td></tr><tr><td>third wash</td><td>2.14</td><td>0.32</td></tr><tr><td>last wash</td><td>4.05</td><td>0.65</td></tr></table>	Wash No.	Residue		[mg]	[%]	Initial	369.10	54.77	first wash	3.68	0.55	second wash	2.82	0.42	third wash	2.14	0.32	last wash	4.05	0.65			
Wash No.	Residue																									
	[mg]	[%]																								
Initial	369.10	54.77																								
first wash	3.68	0.55																								
second wash	2.82	0.42																								
third wash	2.14	0.32																								
last wash	4.05	0.65																								

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

zRMS comment:

In the accelerated storage study the formulation was stored in f-HDPE packaging. Based on the results, this type of packaging is acceptable.

Table 1.6-1: Packaging information for 1 L bottle

Type	Description
Material:	f-HDPE (fluorinated HDPE)
Shape/size:	cylindrical / high 233.2 ±1.6 mm; width 88.5 ±1.0 mm
Opening:	53.1 mm inner diameter
Closure:	HDPE screw cap
Seal:	seal made of foamed polyethylene
Manner of construction	extruded
UN/ADR	compliant

Table 1.6-2: Packaging information for 5 L canister

Type	Description
Material:	f-HDPE (fluorinated HDPE)
Shape/size:	high 305 ±3.0 mm; width 193 ±2.0 mm x 142 ±2.0 mm
Opening:	64 ±0.25 mm inner diameter
Closure:	HDPE screw cap
Seal:	seal made of foamed polyethylene
Manner of construction	extruded
UN/ADR	compliant

Table 1.6-3: Packaging information for 10 L canister

Type	Description
Material:	f-HDPE (fluorinated HDPE)
Shape/size:	high 377.5 ±2.5 mm; width 240 ±2.0 mm x 179 ±2.0 mm
Opening:	63.3 ±0.4 mm inner diameter
Closure:	HDPE screw cap
Seal:	seal made of foamed polyethylene
Manner of construction	extruded
UN/ADR	compliant

Table 1.6-4: Packaging information for 20 L canister

Type	Description
Material:	f-HDPE (fluorinated HDPE)
Shape/size:	high 400 ±3.0 mm; width 293 ±3.0 mm x 245 ±3.0 mm
Opening:	61 mm inner diameter

Type	Description
Closure:	HDPE screw cap
Seal:	seal made of foamed polyethylene
Manner of construction	extruded
UN/ADR	compliant

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.4.1 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 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Condorelli A.M.M.	2023	Determination of the Physical-Chemical properties of H-01-2022 Product Before and after Accelerated Storage for 14 days at 54±2 °C and low temperature storage for 7 days at 0±2°C. Report No. 22363-02C Renolab S.r.l. GLP Published	N	ProAgri Sp. z o. o.
KCP 2.7.1	Condorelli A.M.M.	2025	Amendment No. 1 Final Report 22363-02C. Determination of the Physical-Chemical properties of H-01-2022 Product Before and after Accelerated Storage for 14 days at 54±2 °C and low temperature storage for 7 days at 0±2°C. Renolab S.r.l.	N	ProAgri 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

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

A 2.1 Terbutylazine

No further data available.