REGISTRATION REPORT

Part B

Section 1: Identity
Section 2: Physical and chemical properties
Section 4: Further information

Detailed summary of the risk assessment

Product name(s): PYRIX 20 SL

Chemical active substance:

PYRIPROXYFEN, 20g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: AGROFARM SP. Z O.O.

Submission date: 7 November 2025

MS Finalisation date: July 2026 (initial Core Assessment)

September 2026 (final Core Assessment)

Version history

When	What
07.11.2025	First version
13.03.2026	Update - highlighted in yellow.
July 2026	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
September 2026	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the 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.

Noticed data gaps are:
- No stability study results are available for storage in HDPE/PA packaging over a two-year period.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

[redacted]

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 Active substance Pyriproxyfen

PYRIPROXYFEN min. 980 g/kg

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

Confidential information or data- provided separately (Part C).

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Information on the formulants is confidential and are included in Part C (Confidential information).

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	FAO Limits (min – max)	Technical content in Pyrix 20 SL * (g/L or g/kg)
PYRIPROXYFEN	Min 970 g/kg	20g/L 1.9138%

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers
** Based on the density of the formulation = 1.045 g/cm^3

Table 1.4-2: Safener and synergists

NOT APPLICABLE.

Table 1.4-3: Relevant impurities

NOT APPLICABLE

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured: Toluene: max 5 g/kg.

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

Table 1.4-4: Information on active substance pyriproxyfen

Type	Name/Code Number
ISO common name	Pyriproxyfen (BSI, E-ISO)
Chemical names	IUPAC: 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether CA: 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine
CAS No.	95737-68-1
EC No.	429-800-1
CIPAC No.	715

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

CONFIDENTIAL information- provided separately (Part C).

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

Type: Soluble Liquid [Code: SL]

1.6 Function (KCP 1.6)

Insecticide
Made of action : contact and stomach
Uses: for the control of flies (*Sciaridae*) in mushroom cultivation.

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 liquid color 1, with characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 7.41-7.87 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0±2 °C and 14 days at 54± 2°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 packaging material HDPE/PA. It should be noted, however, that no stability test results are available for storage in HDPE/PA packaging over a two-year period; these data should be provided as soon as they become available.
Its technical characteristics are acceptable for a SL formulation (Pyrix 20 SL).
The intended concentration of use is: 15mL /m2 usind 1 litr of water [1.5% v/v]

Detailed in document:
Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests .
Study code :0012/0004/FA
2025
Author(s): SORBOLAB Research Laboratory LLC ,Poznań, Poland
GLP: YES
Unpublished

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

NOT APPLICABLE.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

NOT APPLICABLE.

Compliance with FAO specifications:

No FAO Specification for pyriproxyfen SL formulation.

Formulation used for tests

Agrofarm declared 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)	based on EPA OPPTS 830.6302 830.6303 830.6304 and Polish Pharmacopoeia VI	PYRIX 20 SL	Physical state: liquid Colour: 1 according to the Gardner System Odour: characteristic	YES	Study code: 0012/0004/FA; 2025	Accepted.
	1 year storage study: SPB-FA/04 based on EPA OPPTS 830.6302 830.6303 830.6304 and Polish Pharmacopoeia VI		**Observations after 1 year storage at temperature of 20±2°C:** Physical state: liquid Colour: 1 according to the Gardner System Odour: characteristic	YES	Study code: 0012/0004/FA, 2026	Accepted.
Explosive properties (KCP 2.2.1)	NOT APPLICABLE	-	Product contains 45% of water. Non-explosive properties of all raw materials are confirmed in manufacturers' technical documentation for materials they produce. Sodium Lauryl Sulphate in air can form an explosive mixture at SLS concentration of 37 g/m^3 and when explosion is initiated by an electrostatic spark. SLS dissolved in water does not have explosive properties. All substances used in Pyrix 20 SL formulation are chemically non-reactive and absolutely stable due to the structure of their molecules.	-	-	Justification acceptable. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Oxidizing properties (KCP 2.2.2)	NOT APPLICABLE	-	All substances used are chemically non-reactive – they do not contain any oxidizing radicals. These characteristics are confirmed by manufacturer's documentation for all raw materials.	-	-	Justification acceptable. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flash point (KCP 2.3.1)	NOT APPLICABLE	-	The product contains 45% water. All technical-grade ingredients have a flash point between 104°C and 340°C. Water vapor pressure is dominant, and the vapor pressure of organic	-	-	Justification acceptable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			components can be considered negligible.			The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flammability (KCP 2.3.2)	NOT APPLICABLE	-	Product is non-flammable due to high (45%) concentration of water and very low vapor pressure of organic substances with very high molecular weights	-	-	Justification acceptable. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Self-heating (KCP 2.3.3)	NOT APPLICABLE	-	All substances used in formulation of Pyrix 20SL are chemically non-reactive and the possibility of their chemical reactions with exothermic effects is not possible.	-	-	Justification acceptable. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Acidity or alkalinity (KCP 2.4.1)	SPB-FA/77 based on CIPAC MT 191	PYRIX 20 SL	Determination wasn't performed because pH of the test item was outside the rage 4-10 (European Parliament and of the Council no. 528/2012)	YES	Study code: 0012/0004/FA; 2025	Accepted.
	1 year storage study: SPB-FA/77 based on CIPAC MT 191		**After 1 year storage at temperature of 20±2°C:** Determination wasn't performed because pH of the test item was in the range 4-10 (European Parliament and of the Council no. 528/2012)	YES	Study code: 0012/0004/FA, 2026	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
pH (directly) (KCP 2.4.1)	SPB-FA/01 based on CIPAC MT 75.3 **1 year storage study:** SPB-FA/01 based on CIPAC MT 75.3	PYRIX 20 SL	7.87 at 20±1ºC **After 1 year storage at temperature of 20±2°C:** **7.9** at 20±1ºC	YES YES	Study code: 0012/0004/FA; 2025 Study code: 0012/0004/FA, 2026	Accepted. Accepted.
Dynamic Viscosity at 20^{O}C [mPa*s] (KCP 2.5.1)	SPB-FA/06 based on OECD 114	PYRIX 20 SL	48.23	YES	Study code: 0012/0004/FA; 2025	Accepted.
Dynamic Viscosity at 40^{O}C [mPa*s] (KCP 2.5.1)			18.16	YES	Study code: 0012/0004/FA; 2025	Accepted.
Kinamatic Viscosity at 20^{O}C [mPa*s] (KCP 2.5.1)	SPB-FA/06 based on OECD 114	PYRIX 20 SL	46.15	YES	Study code: 0012/0004/FA; 2025	Accepted.
Kinematic Viscosity at 40^{O}C [mPa*s] (KCP 2.5.1)			17.44	YES	Study code: 0012/0004/FA; 2025	Accepted.
Surface tension (KCP 2.5.2)	SPB-FA/13 based on OECD 115	PYRIX 20 SL	42.81	YES	Study code: 0012/0004/FA; 2025	Accepted.
Relative density (KCP 2.6.1)	SPB-FA/03 based on OECD 109	PYRIX 20 SL	1.045	YES	Study code: 0012/0004/FA; 2025	Accepted.
Absolute density [g/cm^3] (KCP 2.6.2)	SPB-FA/03 based on OECD 109	PYRIX 20 SL	1.045	YES	Study code: 0012/0004/FA; 2025	Accepted.
Storage Stability after 14 days at 54º C (KCP 2.7.1)	SPB-FA/439 based on CIPAC MT ~~41.1~~ 46.4	PYRIX 20 SL	Concentration 0.8% (v/v): stable solution Concentration 1.0% (v/v): stable Solution	No	Study code: 0012/0004/FA; 2025	Accepted. The product showed no significant physical changes after accelerated storage.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			The determination of the content of the active substance (pyriproxyfen) was performed according to experimental procedure SPB-FA/467. Analytical method was validated in study code 0012/0003/FA based on experimental procedure SPB-FA/11 and guideline SANCO/3030/99 rev. 5.			No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial HDPE/PA packaging.

Parameter	Test method	Results of start tests	Results after stability test at 0±2°C for 7 days	Results after accelerated aging at 54±2°C for 2 weeks
Determination of content of the active substance (pyriproxyfen) [% (w/w)]	SPB-FA/467 based on validated method (study code 0012/0003/FA)	1.94	-	1.96
Organoleptic properties	SPB-FA/04 based on EPA OPPTS 830.6302 830.6303 830.6304 and Polish Pharmacopoeia VI	Physical state: liquid Colour: 1 according to the Gardner System Odour: characteristic	-	Physical state: liquid Colour: 1 according to the Gardner System Odour: characteristic
pH (directly)	SPB-FA/01 based on CIPAC MT 75.3	7.87	-	7.41
Acidity/Alkalinity	SPB-FA/77 based on CIPAC MT 191	Determination wasn't performed because pH of the test item was outside the rage 4-10 (European Parliament and of the Council no. 528/2012)	-	Determination wasn't performed because pH of the test item was outside the rage 4-10 (European Parliament and of the Council no. 528/2012)
Relative density	SPB-FA/03 based on OECD 109	1.045	-	-
Absolute density [g/cm³]	SPB-FA/03 based on OECD 109	1.045	-	-
Dynamic viscosity at 20°C [mPa*s]	SPB-FA/06 based on OECD 114	48.23	-	-
Dynamic viscosity at 40°C [mPa*s]		18.16	-	-

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th>Parameter</th><th>Test method</th><th>Results of start tests</th><th>Results after stability test at 0±2°C for 7 days</th><th>Results after accelerated aging at 54±2°C for 2 weeks</th></tr>
<tr><td>Kinematic viscosity at 20°C [mm²/s]</td><td rowspan="2">SPB-FA/06 based on OECD 114</td><td>46.15</td><td>-</td><td>-</td></tr>
<tr><td>Kinematic viscosity at 40°C [mm²/s]</td><td>17.44</td><td>-</td><td>-</td></tr>
<tr><td>Surface tension [mN/m]</td><td>SPB-FA/13 based on OECD 115</td><td>42.81</td><td>-</td><td>-</td></tr>
<tr><td>Foam persistence [mL]</td><td>SPB-FA/59 based on CIPAC MT 47.3</td><td>Foam stability for 0.8% (w/v) after
0 s: 50
1 min±10 s: 44
12 min ±10 s: 36

Foam stability for 1% (w/v) after
0 s: 56
1 min±10 s: 44
12 min ±10 s: 39</td><td>-</td><td>-</td></tr>
<tr><td>Stability of solution</td><td>SPB-FA/439 based on CIPAC MT 41.1</td><td>Concentration 0.8% (v/v): stable solution
Concentration 1.0% (v/v): stable solution</td><td>-</td><td>Concentration 0.8% (v/v): stable solution
Concentration 1.0% (v/v): stable solution</td></tr>
<tr><td>Packaging appearance</td><td rowspan="2">SPB-FA/14 based on OPPTS 830.6320 Corrosion characteristics</td><td>Type of material: PE/PA
Shape: cylindrical
Colour: white
Type of closure: white cap with thread
White label with legible lettering
No damage</td><td>-</td><td>Type of material: PE/PA
Shape: cylindrical
Colour: white
Type of closure: white cap with thread
White label with legible lettering
No damage</td></tr>
<tr><td>Weight loss after storage [%]</td><td>-</td><td>-</td><td>0.10</td></tr>
</table>
<table>
<tr><th>Parameter</th><th>Test method</th><th>Results of start tests</th><th>Results after stability test at 0±2°C for 7 days</th><th>Results after accelerated aging at 54±2°C for 2 weeks</th></tr>
<tr><td>Stability at 0±2°C for 7 days</td><td>SPB-FA/08 based on CIPAC MT 39.3.</td><td>-</td><td>Average storage temperature -0.4°C (temperature max: 0.6°C; temperature min: -1.3°C) (The test item was homogeneous, clear, no precipitations were observed)</td><td>-</td></tr>
<tr><td>Accelerated aging at 54±2°C for 2 weeks</td><td>SPB-FA/07 based on CIPAC MT 46.4</td><td>-</td><td>-</td><td>average storage temperature: 53.5°C
max. temperature: 53.7°C
min. temperature: 51.6°C!</td></tr>
</table>
</td><td></td><td></td><td></td></tr>
<tr><td>Stability -start test at 20^{O}C
(KCP 2.7.2)</td><td>SPB-FA/439 based on CIPAC MT 41.1</td><td>PYRIX 20 SL</td><td>Concentration 0.8% (v/v): stable solution
Concentration 1.0% (v/v): stable solution</td><td>No</td><td>Study code: 0012/0004/FA; 2025</td><td></td></tr>
</table>

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td>Minimum content after heat stability testing (KCP 2.7.3)</td><td>SPB-FA/467 based on validated method (study code 0012/0003/FA)</td><td>PYRIX 20 SL</td><td>1.96</td><td>YES</td><td>Study code: 0012/0004/FA; 2025</td><td>Accepted.</td></tr>
<tr><td>Effect of low temperatures on stability (KCP 2.7.4)</td><td>~~Not relevant~~
CIPAC MT 39.3; SPB/08</td><td>PYRIX 20 SL</td><td>Not relevant
Pyrinex 20SL should be stored at a temperature between 0°C and 30°C.</td><td>-</td><td>-</td><td>Accepted.</td></tr>
<tr><td>Ambient temperature shelf life

Storage at temperature of 20±2°C for 1 year (KCP 2.7.5)</td><td>SPB-FA/09 based on CropLife International Technical Monograph No 17, 3rd Edition and OECD Guidance Document for Storage Stability Testing of Plant Protection and Biocidal Products - Guidance Used in Support of Pre-registration Data Requirements for Plant Protection and Biocidal End-use Products</td><td>PYRIX 20 SL</td><td>Mean temperature of storage: 19.0°C
(minimum temperature: 18.1°C
maximum temperature: 22.1°C1)

<table>
<tr><th>Parameter</th><th>Test method</th><th>Results (after 1 year of storage at temperature of 20±2°C)</th></tr>
<tr><td>Determination of content of the active substance (pyriproxyfen) [% (w/w)]</td><td>SPB-FA/467 based on validated method (study code 0012/0003/FA)</td><td>1.94</td></tr>
<tr><td>Organoleptic properties</td><td>SPB-FA/04 based on EPA OPPTS 830.6302 830.6303 830.6304 and Polish Pharmacopoeia VI</td><td>Physical state: liquid
Colour: 1 according to the Gardner System
Odour: characteristic</td></tr>
<tr><td>pH (directly)</td><td>SPB-FA/01 based on CIPAC MT 75.3</td><td>7.9</td></tr>
<tr><td>Acidity/Alkalinity</td><td>SPB-FA/77 based on CIPAC MT 191</td><td>Determination wasn't performed because pH of the test item was in the range 4-10 (European Parliament and of the Council no. 528/2012)</td></tr>
<tr><td>Stability of solution</td><td>SPB-FA/439 based on CIPAC MT 41.1</td><td>Concentration 0.8% (v/v): stable solution
Concentration 1.0% (v/v): stable solution</td></tr>
<tr><td>Packaging appearance</td><td rowspan="2">SPB-FA/14 based on OPPTS 830.6320 Corrosion characteristics</td><td>Type of material: PE/PA
Shape: cylindrical
Colour: white
Type of closure: white cap with thread
White label with legible lettering
No damage</td></tr>
<tr><td>Weight loss after storage [%]</td><td>0.1</td></tr>
</table></td><td>YES</td><td>Study code: 0012/0004/FA, 2026</td><td>Accepted.
The product showed no significant physical changes after 1 year of storage.

No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial HDPE/PA packaging.

However, in order to confirm the two-year storage stability period, the stability results after two-year of storage must be provided when they become available.</td></tr>
</table>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<table><tr><th>Parameter</th><th>Test method</th><th>Results (after 1 year of storage at temperature of 20±2°C)</th></tr><tr><td>Foam persistence [mL]</td><td>SPB-FA/59 based on CIPAC MT 47.3</td><td>For 0.8% (w/v) after 0 s: 50 1 min±10 s: 41 12 min ±10 s: 35 For 1% (w/v) after 0 s: 54 1 min±10 s: 48 12 min ±10 s: 37</td></tr><tr><td>Storage at temperature of 20±2°C for 1 year</td><td>SPB-FA/09 based on CropLife International Technical Monograph No 17, 3rd Edition and OECD Guidance Document for Storage Stability Testing of Plant Protection and Biocidal Products - Guidance Used in Support of Pre-registration Data Requirements for Plant Protection and Biocidal End-use Products</td><td>Mean temperature of storage: 19.0°C (minimum temperature: 18.1°C maximum temperature: 22.1°C[1])</td></tr></table> The determination of the content of the active substance (pyriproxyfen) was performed according to experimental procedure SPB-FA/467. Analytical method was validated in study code 0012/0003/FA based on experimental procedure SPB-FA/11 and guideline SANCO/3030/99 rev. 5.			
Determination of content of the active substance (pyriproxyfen) [% (w/w)] after 1 year of storage at temperature of 20±2°C (KCP 2.7.5)	SPB-FA/467 based on validated method (study code 0012/0003/FA)	PYRIX 20 SL	1.94	YES	Study code: 0012/0004/FA, 2026	Accepted
~~Stability of solution after 1 year of storage at temperature of 20±2°C (KCP 2.7.5)~~	~~SPB-FA/439 based on CIPAC MT 41.1~~	~~PYRIX 20 SL~~	~~Concentration 0.8% (v/v): stable solution~~ ~~Concentration 1.0% (v/v): stable solution~~	~~YES~~	~~Study code: 0012/0004/FA, 2026~~	-
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable	-	Not applicable	-	-	-
Wettability (KCP 2.8.1)	Not applicable	-	Not applicable	-	-	-
Persistence of foaming [mL] (KCP 2.8.2)	SPB-FA/59 based on CIPAC MT 47.3	PYRIX 20 SL	~~Foam stability for 0.8% (w/v) after~~ ~~0 s: 132~~ ~~1 min±10 s: 107~~ ~~12 min ±10 s: 94~~	NO	Study code: 0012/0004/FA; 2025	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Foam persistence [mL] after 1 year of storage at temperature of 20±2°C (KCP 2.8.2)	SPB-FA/59 based on CIPAC MT 47.3		~~Foam stability for 1% (w/v) after~~ ~~0 s: 175~~ ~~1 min±10 s: 137~~ ~~12 min ±10 s: 125~~ For 0.8% (w/v) after 0 s: 50 1 min±10 s: 41 12 min ±10 s: 35 For 1% (w/v) after 0 s: 54 1 min±10 s: 48 12 min ±10 s: 37	YES	Study code: 0012/0004/FA, 2026	Accepted

Time of observation [min]	Measurement foam persistence in Standard Water C				Mean foam persistence [mL]
	No. I		No. II		
	Weight of the test item [g]	Foam persistence [mL]	Weight of the test item [g]	Foam persistence [mL]	
Concentration of the test item solution: 0.8% (w/v)					
0	1.6	50	1.6	50	50
1		44		44	44
12		36		36	36
Concentration of the test item solution: 1.0% (w/v)					
0	2.0	56	2.0	56	56
1		44		44	44
12		39		39	39

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<table><tr><th rowspan="3">Time of observation [min]</th><th colspan="4">Measurement foam persistence in Standard Water C*</th><th rowspan="3">Mean foam persistence [mL]</th></tr><tr><th colspan="2">No. I</th><th colspan="2">No. II</th></tr><tr><th>Weight of the test item [g]</th><th>Foam persistence [mL]</th><th>Weight of the test item [g]</th><th>Foam persistence [mL]</th></tr><tr><td colspan="6">Concentration of the test item solution: 0.8% (w/v)</td></tr><tr><td>0</td><td rowspan="3">1.6</td><td>50</td><td rowspan="3">1.6</td><td>49</td><td>50</td></tr><tr><td>1</td><td>44</td><td>38</td><td>41</td></tr><tr><td>12</td><td>35</td><td>35</td><td>35</td></tr><tr><td colspan="6">Concentration of the test item solution: 1.0% (w/v)</td></tr><tr><td>0</td><td rowspan="3">2.0</td><td>54</td><td rowspan="3">2.0</td><td>53</td><td>54</td></tr><tr><td>1</td><td>46</td><td>49</td><td>48</td></tr><tr><td>12</td><td>38</td><td>36</td><td>37</td></tr></table>			
Suspensibility (KCP 2.8.3.1)	Not applicable	-	Not applicable	-	-	-
Spontaneity of dispersion (KCP 2.8.3.2)	Not applicable	-	Not applicable	-	-	-
Dispersion stability (KCP 2.8.3.3)	Not applicable	-	Not applicable	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	~~Not applicable~~ SPB-FA/439 Based on CIPAC MT 41.1; Standard Water D	PYRIX 20 SL	~~Not applicable~~ Concetration 0.8% (v/v): stable solution Concentration 1.0% (v/v): stable solution <table><tr><th>No.</th><th>Sediment volume after 30 min [mL]</th><th>Sediment volume after 24 h [mL]</th></tr><tr><td colspan="3">Concentration of the test item solution: 0.8% (v/v)</td></tr><tr><td>1</td><td>no sediment</td><td>no sediment</td></tr><tr><td>2</td><td>no sediment</td><td>no sediment</td></tr><tr><td colspan="3">Concentration of the test item solution: 1.0% (v/v)</td></tr><tr><td>1</td><td>no sediment</td><td>no sediment</td></tr><tr><td>2</td><td>no sediment</td><td>no sediment</td></tr></table> Table 15. Stability of solution - after accelerated aging at temperature 54±2°C for 2 weeks <table><tr><th>No.</th><th>Sediment volume after 30 min [mL]</th><th>Sediment volume after 24 h [mL]</th></tr><tr><td colspan="3">Concentration of the test item solution: 0.8% (v/v)</td></tr><tr><td>1</td><td>no sediment</td><td>no sediment</td></tr><tr><td>2</td><td>no sediment</td><td>no sediment</td></tr><tr><td colspan="3">Concentration of the test item solution: 1.0% (v/v)</td></tr><tr><td>1</td><td>no sediment</td><td>no sediment</td></tr><tr><td>2</td><td>no sediment</td><td>no sediment</td></tr></table>	NO	Study code: 0012/0004/FA; 2025	Accepted.
	SPB-FA/439	PYRIX 20 SL	Concentration 0.8% (v/v): stable solution Concentration 1.0% (v/v): stable solution	Yes	Study code: 0012/0004/FA, 2026	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	based on CIPAC MT 41.1		<table><tr><th>No.</th><th>Sediment volume after 30 min [mL]</th><th>Sediment volume after 24 h [mL]</th></tr><tr><td colspan="3">Concentration of the test item solution: 0.8% (v/v)</td></tr><tr><td>1</td><td>no sediment</td><td>no sediment</td></tr><tr><td>2</td><td>no sediment</td><td>no sediment</td></tr><tr><td colspan="3">Concentration of the test item solution: 1.0% (v/v)</td></tr><tr><td>1</td><td>no sediment</td><td>no sediment</td></tr><tr><td>2</td><td>no sediment</td><td>no sediment</td></tr></table>			
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not applicable	-	Not applicable	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	Not applicable	-	Not applicable	-	-	-
Dust content (KCP 2.8.5.2.1)	Not applicable	-	Not applicable	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	Not applicable	-	Not applicable	-	-	-
Attrition (KCP 2.8.5.3)	Not applicable	-	Not applicable	-	-	-
Hardness and integrity (KCP 2.8.5.4)	Not applicable	-	Not applicable	-	-	-
Emulsifiability (KCP 2.8.6.1)	Not applicable	-	Not applicable	-	-	-
Emulsion stability (KCP 2.8.6.2)	Not applicable	-	Not applicable	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	Not applicable	-	Not applicable	-	-	-
Flowability (KCP 2.8.7.1)	Not applicable	-	Not applicable	-	-	-
Pourability (KCP 2.8.7.2)	Not applicable	-	Not applicable	-	-	-
Dustability following accelerated storage (KCP 2.8.7.3)	Not applicable	-	Not applicable	-	-	-

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td>Physical compatibility of tank mixes
(KCP 2.9.1)</td><td>Not applicable</td><td>-</td><td>Not applicable</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Chemical compatibility of tank mixes
(KCP 2.9.2)</td><td>Not applicable</td><td>-</td><td>Not applicable</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Adhesion to seeds
(KCP 2.10.1)</td><td>Not applicable</td><td>-</td><td>Not applicable</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Distribution to seed
(KCP 2.10.2)</td><td>Not applicable</td><td>-</td><td>Not applicable</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Other/special studies
Packaging appearance at 20^{O}C and after 2 weeks after 54^{O}C
(KCP 2.11)</td><td>SPB-FA/14 based on OPPTS 830.6320 Corrosion characteristics</td><td>PYRIX 20 SL</td><td>Type of material: PE/PA
Shape: cylindrical
Colour: white
Type of closure: white cap with thread
White label with legible lettering
No damage
<table><tr><th>Parameter</th><th>Before storage</th><th>After accelerated aging at the temperature 54±2°C for 2 weeks</th></tr><tr><td>Type of material</td><td>PE/PA</td><td>PE/PA</td></tr><tr><td>Shape/form</td><td>shape cylindrical</td><td>shape cylindrical</td></tr><tr><td>Type of closure</td><td>white cap with thread</td><td>white cap with thread</td></tr><tr><td>Colour</td><td>white</td><td>white</td></tr><tr><td>Readability of labels/inscriptions</td><td>white label with legible lettering</td><td>white label with legible lettering</td></tr><tr><td>Potential damages/defects</td><td>no damage</td><td>no damage</td></tr></table></td><td>NO</td><td>Study code: 0012/0004/FA; 2025</td><td>Accepted.

It should be noted that, in the current format of the report, the assessment of packaging applies to sections 2.7.1, 2.7.5 and 4; however, as the data has been inserted here by the applicant, we have decided not to move it.</td></tr>
<tr><td>Other/special studies
Weight loss after 2 weeks of storage at 54^{O}C [%]
(KCP 2.11)</td><td>SPB-FA/14 based on OPPTS 830.6320 Corrosion characteristics</td><td>PYRIX 20 SL</td><td>0.10</td><td>NO</td><td>Study code: 0012/0004/FA; 2025</td><td>Accepted.

It should be noted that, in the current format of the report, the assessment of packaging applies to sections 2.7.1, 2.7.5 and 4; however, as the data has been inserted here by the applicant,</td></tr>
</table>

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>we have decided not to move it.</td></tr>
<tr><td>Other/special studies
Packaging appearance after 1 year of storage at temperature of 20±2°C (KCP 2.7.5)</td><td>SPB-FA/14 based on OPPTS 830.6320 Corrosion characteristics</td><td>PYRIX 20 SL</td><td>Type of material: PE/PA
Shape: cylindrical
Colour: white
Type of closure:
white cap with thread
White label with legible lettering
No damage
<table><tr><th>Parameter</th><th>Result</th></tr><tr><td>Type of material</td><td>PE/PA</td></tr><tr><td>Shape/form</td><td>shape cylindrical</td></tr><tr><td>Type of closure</td><td>white cap with thread</td></tr><tr><td>Colour</td><td>white</td></tr><tr><td>Readability of labels/inscriptions</td><td>white label with legible lettering</td></tr><tr><td>Potential damages/defects</td><td>no damage</td></tr></table></td><td>NO</td><td>Study code: 0012/0004/FA, 2026</td><td>Accepted.

It should be noted that, in the current format of the report, the assessment of packaging applies to sections 2.7.1, 2.7.5 and 4; however, as the data has been inserted here by the applicant, we have decided not to move it.</td></tr>
<tr><td>Other/special studies
Weight loss after storage [%] after 1 year of storage at temperature of 20±2°C (KCP 2.7.5)</td><td>SPB-FA/14 based on OPPTS 830.6320 Corrosion characteristics</td><td>PYRIX 20 SL</td><td>0.1</td><td>NO</td><td>Study code: 0012/0004/FA, 2026</td><td>Accepted.

It should be noted that, in the current format of the report, the assessment of packaging applies to sections 2.7.1, 2.7.5 and 4; however, as the data has been inserted here by the applicant, we have decided not to move it.</td></tr>
</table>

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)

Comments of zRMS:	• No stability study results are available for storage in HDPE/PA packaging over a two-year period; • No stability study results (accelerated and stability study results after two years of storage) are available for HDPE packaging. The accelerated stability data and stability after 12 months of storage indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging HDPE/PA. SANCO/10473/2003 rev.6, 20 January 2026 for SL formulation: For aqueous based formulation types e.g. SL, SC, LS, CS or FS, extrapolation between any plastic material types is acceptable. In view of the above, all the proposed packaging can be accepted.

Table 4.1-1: Packaging information for 1L bottle

Type	Description
Material:	PA/PE (Coex) or HDPE
Shape/size:	cylindrical / approx. 63 mm diameter x 92 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap/ polypropylene screw cap with foamed polyethylene liner
Seal:	HF-seal
Manner of construction	extrusion (side injection) or blowing (blowing)
UN/ADR	Compliant -YES

Table 4.1-2: Packaging information for 5L canister

Type	Description
Material:	HDPE or HDPE+ Polyamide plastic which can be replaced with EVOH barrier if needed
Shape/size:	rectangular -dimension: 14-17cm x 19-22cm/ high 25-32cm (weight 200- 220g)
Opening:	35 to 54mm inner neck diameter
Closure:	polyethylene screw cap/ polypropylene screw cap with foamed polyethylene liner
Seal:	HF-seal
Manner of construction	extrusion or blowing or extrusion blow moulding
UN/ADR	Compliant -YES

Table 4.1-3: Packaging information for 10L canister

Type	Description
Material:	HDPE or HDPE +Polyamide plastic which can be replaced with EVOH barrier if needed
Shape/size:	rectangular -dimension: 17-19cm x 23-25cm/ high 28,5-37,5cm (weight 360g- 460g)
Opening:	35 to 54mm inner neck diameter
Closure:	polyethylene screw cap/ polypropylene screw cap with foamed polyethylene liner
Seal:	HF-seal
Manner of construction	extrusion/ blowing / extrusion blow moulding
UN/ADR	Compliant- YES

Table 4.1-4: Packaging information for 20L canister

Type	Description
Material:	HDPE or HDPE/PA
Shape/size:	rectangular - approximate dimensions (H x L x W): 39,0 x 26,5 x 26,5 cm 39,0 x 28,9 x 26,0 cm 38,0 x 29,5 x 24,6 cm (weight 850g- 950g)
Opening:	60-61mm inner neck diameter (DIN)
Closure:	polyethylene screw cap/ polypropylene screw cap with foamed polyethylene liner
Seal:	HF-seal
Manner of construction	extrusion/ blowing / extrusion blow moulding
UN/ADR	Compliant- YES

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	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.1	Magdalena Legan, Marzena Włodarczak/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2026	Report (after 1 year of storage at temperature of 20±2°C) Determination of the physicochemical properties of the test item PYRIX 20SL before and after stability test . Study code :0012/0004/FA GLP-YES Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.4.1	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.4.1	Magdalena Legan, Marzena Włodarczak/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2026	Report (after 1 year of storage at temperature of 20±2°C) Determination of the physicochemical properties of the test item PYRIX 20SL before and after stability test . Study code :0012/0004/FA GLP-YES Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.5.1	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.5.2	M.Legan, MWło-darczyk/ SORBOLAB Research	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA	N	Agrofarm 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
	Laboratory LLC ,Poznań, Poland		GLP- Yes Unpublished		
KCP 2.6.1	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.6.2	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.7.1	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.7.2	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.7.3	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.7.5	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.7.5	Magdalena Legan,	2026	Report (after 1 year of storage at temperature of 20±2°C)	N	Agrofarm

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
	Marzena Włodarczak/ SORBOLAB Research Laboratory LLC ,Poznań, Poland		Determination of the physicochemical properties of the test item PYRIX 20SL before and after stability test . Study code :0012/0004/FA GLP-YES Unpublished		Sp. z o.o.
KCP 2.8.2	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.8.2	Magdalena Legan, Marzena Włodarczak/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2026	Report (after 1 year of storage at temperature of 20±2°C) Determination of the physicochemical properties of the test item PYRIX 20SL before and after stability test . Study code :0012/0004/FA GLP-YES Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.11	M.Legan, MWło-darczyk/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2025	Report (start tests, stability at 0˚C, accelerated aging 54˚C).Determination of the physicochemical properties of the test item PYRIX 20 SL before and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished	N	Agrofarm Sp. z o.o.
KCP 2.11	Magdalena Legan, Marzena Włodarczak/ SORBOLAB Research Laboratory LLC ,Poznań, Poland	2026	Report (after 1 year of storage at temperature of 20±2°C) Determination of the physicochemical properties of the test item PYRIX 20SL before and after stability test . Study code :0012/0004/FA GLP-YES Unpublished	N	Agrofarm 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
-	-	-	-	-	-

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 Active substance pyriproxyfen

NOT APLLICABLE.

Agrofarm Sp. z o.o. has data access to Pyriproxyfen active concentrate which has been approved at the EU level

See PART C - Confidential Information

- Letter of Supply and data Access to Pyriproxyfen active concentrate Issued to Agrofarm Sp. z o.o., Dzika 41/48, 00-194 Warszawa, Poland – 14 October 2025.
- Letter form EU DG-Animals,Plants and Food.Plant Protection Product and Fertilisers: Evaluation of the equivalence of new source of the active substance pyriproxyfen. Ref.:41.500/16/256945 ; 01-08-2016