REGISTRATION REPORT

Part A

Risk Management

Product name(s): PYRIX 20SL

Chemical active substance(s):

Pyriproxyfen 20 g/L

Central Zone

Zonal Rapporteur Member State: Poland

Applicant: AGROFARM SP. Z O.O.

Submission date: November 2025, updated October 2026

MS Finalisation date: July 2026 (initial National Assessment)

September 2026, updated October 2026 (final National Assessment)

Version history

When	What
November 2025	Initial dRR – Agrofarm Sp. z o.o.
June 2026	Correction – point 2.4.1 – changes are highlighted in green.
July 2026	Initial zRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey, while not agreed use pattern is ~~struck through~~ and shaded. 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 (National Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
October 2026	Information changes by applicant (in green) in Appendix 4 - Lists of data considered for national authorization: a) entering all tables in the "Justification" column: - wasn't used in the assessment of another PPP b) new entry in point 1.1.2 in the PART C table: - Data never submitted before to Poland or other country registration office and wasn't used in the assessment of another PPP c) new entry in the PART C table, line/point 1.1.2/1.1.3: - Information available upon submission of an access request and marked as "unprotected" d) new entry in point1.1.2,1.1.3 in the PART C table; 1.2.1 and 1.2.3: - Data never submitted before to Poland or other country registration office and wasn't used in the assessment of another PPP
October 2026	Transfer of changes from the list of studies in Part A, received from the applicant via MRiRW, to the zRMS version dated September 2026. Changes are highlighted in green. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

The dossier has been submitted according Art.33 REGULATION (EC) No 1107/2009. It's written for Mamber State Poland for authorisation of plant protection product PYRIX 20 SL.

The intended use of PYRIX 20 SL is to control flies (*Sciaridae*) in mushroom cultivation. The product is intended for professional use.

Although mushroom cultivation has historically been classified under "greenhouse" cultivation (Reg. (EC) No 1107/2009, Article 3, Definition 27), recent regulatory guidance and the technical realities of mushroom farming strongly support its classification as a closed building use for the purpose and intended uses of our Plant Protection Product *Pyriproxyfen 20 SL*.
In fact, the EFSA (2019) administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances explicitly lists "mushroom sheds" as an example of indoor use, alongside other enclosed environments such as silos and storage rooms.

> *"For indoor use the remarks column should contain an entry to clarify the use e.g. post-harvest storage room or silo, potato store, mushroom shed, witloof shed or rhubarb forcing house."*

This reflects a shift in regulatory understanding that mushroom cultivation occurs in fully enclosed, controlled environments, distinct from traditional greenhouses and as such, environmental exposure is negligible.

Mushroom growing houses are modernly designed for efficient cultivation and are therefore located in buildings that are isolated from the external environment. Such buildings are fully closed with non-transparent walls and a non-transparent roof, with a tightly sealed, smooth concrete floor most often covered with ceramic tiles. The growing rooms are equipped with the necessary air conditioning and irrigation systems with a microclimate control system.
Unlike greenhouses, which often have transparent walls and roofs, soil or hydroponic systems with continuous water flow, and thus potential for environmental emissions, mushroom growing houses are:

- opaque, sealed structures,
- using composted substrate on solid, hole-free shelves arranged on several stacked levels,
- using computer-controlled low-water systems, where water is added only to maintain substrate humidity, and not to irrigate.

The solid, hole-free shelves as well as the computerised low-water systems prevent nutrients from being washed away, thus also preventing pyriproxyfen residues from flowing onto the lower shelves or onto the sealed floors.
These differences make mushroom cultivation chambers functionally and structurally distinct from greenhouses.This all points more towards CLOSED BUILDING.

The planned use and application location of the plant protection product PYRIX 20 SL excludes consideration and risk assessment based on agronomic and environmental conditions in individual zones. This applies to crops grown in advanced facilities, which include greenhouses with a permanent structure, isolated from the ground, and, in relation to the division indicated in the EFSA guideline, so-called "high technology greenhouses" and "low technology greenhouses," both for soilless crops and in ground greenhouses [according to *"Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation of products of these active*

substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments" (EFSA Journal 2014;12(3):3615)].

These assumptions lead to a cross-zonal evaluation of registration dossiers by a single EU Member State. As izRMS Agrofarm chose Poland.

1.2 Letters of Access

Agrofarm has a Letter of Supply and data access to Pyriproxyfen from Tagros Chemicals India Private Limited TAGROS, which is accepted at EU level. For details see APPENDIX 3.

1.3 Justification for submission of tests and studies

Not relevant for tests and study report for active substance pyriproxyfen- Agrofarm have been granted access in accordance with Articles 59,60.
Not relevant for test or study involving vertebrate animals= not submitted.

Agrofarm provide the following information:
- all necessary data for the identification of the plant protection product including its complete composition as well as a declaration that no unacceptable co-formulants are used,
- a complete and a summary dossier for each point of the data requirements of the plant protection product,
- efficacy study,
- residues study reports,
- exposure assessments for operator, worker and bystander
- a draft of label,

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.
Additionally, Agrofarm submits a separate data protection request in Polish.

2 Details of the authorization decision

2.1 Product identity

Product code	-
Product name in MS	PYRINEX 20 SL
Authorization number	n/a
Function	insecticide
Applicant	Agrofarm Sp. z o.o.
Active substance(s) (incl. content)	Pyriproxyfen; 20g/L
Formulation type	soluble liquid [SL]
Packaging	size: 1L bottle/5L canister /10L canister/ 20L canister PA/PE (Coex)/ HDPE or HDPE+ Polyamide plastic which can be replaced with EVOH barrier if needed professional user 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.
Coformulants of concern for national authorizations	n/a
Restrictions related to identiy	n/a
Mandatory tank mixtures	n/a
Recommended tank mixtures	n/a

2.2 Conclusion

The evaluation of the application Pyrix 20 SL resulted in the decision to grant the authorisation. For the details please see column 15 of the GAP table presented in Point 2.6 of this document.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Pyrix 20 SL does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** amending **Annex III** to Regulation (EC) No 1107/2009.
According to the current knowledge and available information none of the co-formulants in the plant protection product Pyrix 20 SL meets the Annex to **Regulation (EU) 2023/574** criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

The plant protection product was assessed for compliance with Commission Regulation (EU) 2023/707. The evaluation included verification of the active substance and relevant co-formulants against the new hazard classes (ED HH, ED ENV, PBT, vPvB, PMT, vPvM). No change in classification was identified.

Detailed assessment of co-formulants according to Article 3 of **Regulation (EU) 2023/574** can be found in annex to Part C of this submission.

The plant protection product does not contain any of the substances listed as safeners and synergists.

Environmental fate and behaviour:
The collected wastewater (after cleaning of the chambers) shall be collected and disposed of in accordance with applicable national waste regulation, by transfer to an entity authorised to collect and manage hazardous waste.

2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with COMMISSION DELEGATED REGULATION (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures derived by calculation (for details refer Part C, p.20)

Hazard class(es), categories	Eye irritation Hazard category 2 Hazardous to the aquatic environment – long-term (chronic) aquatic hazard; Hazard category 1
Hazard pictograms:	GHS07 GHS09
Signal word:	Warning

Hazard statement(s):	H319: Causes serious eye irritation H410: Very toxic to aquatic life with long-lasting effects
Precautionary statement(s):	P264 Wash hands thoroughly after handling. P273 - Avoid release to the environment. P280 Wear eye protection/face protection. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention. P391 – Collect spillage. P501 – Dispose of contents/container in accordance with national regulation

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to human and the environment, comply with the instructions for use.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

Not Applicable.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Not Applicable.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	Wear protective gloves/eye protection/face protection Code:n/a
Worker protection:	
respective code if available	not required (possibly gloves)
Integrated pest management (IPM)/sustainable use:	
respective code if available	n/a
Environmental protection	
respective code if available	n/a
Other specific restrictions	
respective code if available	n/a

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
respective code if available	Not Applicabble

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
respective code if available	Not Applicable	Not Applicable
Environmental protection:		Relevant for use no.
respective code if available	The collected wastewater (after cleaning of the chambers) shall be collected and disposed of in accordance with applicable national waste regulation, by transfer to an entity authorised to collect and manage hazardous waste.	Not Applicable

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1, date: 2026-07 ~~2025-07-10~~

PPP (product name/code):	PYRIX 20 SL	Formulation type:	SL
Active substance 1:	pyriproxyfen	Conc. of as 1:	20 g/L
Safener:	No	Conc. of safener:	n.a.
Synergist:	No	Conc. of synergist:	n.a.
Applicant:	Agrofarm Sp. z o.o.	Professional use:	☒
Zone(s):	Climatic zone: Northern / authorization zone: Central	Non professional use:	☐
Verified by MS:	Yes		
Field of use:	Insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha (f)	**zRMS Conclusions**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/ season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem / Analytical methods / Toxicology / Residues / Fate & behaviour / Ecotoxicology / Relevance of metabolites in groundwater / Efficacy
Climatic zone: Northern/authorization zone: Central (use in greenhouses or other closed places of plant production)														
1	PL	Mushrooms (fungi) Agaricus bisporus	I-indoor application-closed buildings (only professional use)	- sciarid fly (Sciaridae) - phorid fly ~~phyrid fly~~ (Phoridae) Developmental stage: Adult insect	Spray/ manual sprayer	BBCH: overgrowth of cover by mushroom mycelium Spraying two days after applying peat cover ~~a torf cover~~	a) 1 b) 1/1 cycle (3-4 throws= fruit harvest)	n.a.	a) 15 ml/m2 b) 15 ml/m2 for 1 cycle (3-4 fruit harvest)	a) 0,3 g ~~s.a.~~ a.s./m^2 (3 kg/ha or 3000 g/ha) b) 0,3 g ~~s.a.~~ a.s./m^2 (3kg/ha or 3000 g/h) for 1 cycle (3-4 fruit harvest)	(10000 L/ha) 1L/m^2	n.a.		A / R / A / R / A / A / A / A

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions
15 zRMS conclusions*

* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

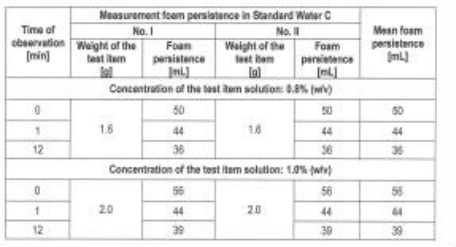
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product: is liquid color 1, with characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it 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]

Implications for labelling: None

Compliance with FAO specifications: The product complies with FAO specifications.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submit-ted, evaluated and is considered to be acceptable.

Colour and physical state (KCP 2.1)	Physical state: liquid Colour: 1 according to the Gardner System Odour: characteristic
Acidity or alkalinity (KCP 2.4.1)	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)
pH (directly) (KCP 2.4.1)	7.87
Dynamic Viscosity at 20^{O}C [mPa*s] (KCP 2.5.1)	48.23
Dynamic Viscosity at 40^{O}C [mPa*s] (KCP 2.5.1)	18.16
Kinamatic Viscosity at 20^{O}C [mPa*s] (KCP 2.5.1)	46.15
Kinematic Viscosity at 40^{O}C [mPa*s] (KCP 2.5.1)	17.44
Surface tension (KCP 2.5.2)	42.81
Relative density (KCP 2.6.1)	1.045
Absolute density [g/cm^{3}] (KCP 2.6.2)	1.045
Degree of dissolution and dilution stability (KCP 2.8.4)	Concentration 0.8% (v/v): stable solution Concentration 1.0% (v/v): stable solution
Degree of dissolution and dilution stability (KCP 2.8.4)	Concentration 0.8% (v/v): stable solution Concentration 1.0% (v/v): stable solution
Minimum content after heat stability testing(KCP 2.7.3)	1.96
Ambient temperature shelf life (KCP 2.7.5)	PENDING
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable

Persistence of foaming [mL] (KCP 2.8.2)	
Other/special studies Packaging appearance at 20^{O}C and after 2 weeks after 54^{O}C (KCP 2.11)	Type of material: HDPE/PA Shape: cylindrical Colour: white Type of closure: white cap with thread White label with legible lettering No damage
Other/special studies Weight loss after 2 weeks of storage at 54^{O}C [%]	0.10

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

3.2 Efficacy (Part B, Section 3)

Pursuant to the Regulation of the Minister of Agriculture and Rural Development of September 18, 2019, amending the Regulation on Minor Uses of Plant Protection Products, mushrooms are classified as minor crops, which allows for a reduction in the number of efficacy trials.
The number of required efficacy trials is specified in EPPO Guideline PP1/226(1) Number of Efficacy Trials.

If the active substance has not been used in a given area (in a given crop), the maximum number of trials is required. Fortunately, in the case of mushrooms, this is only six, as they are classified as minor crops (in accordance with the Regulation on Minor Uses of Plant Protection Products). Of course, six is the minimum required; just in case, one or two more trials can be conducted. The trials must be conducted in at least two cycles.

Comment: Although internal regulations of the Ministry of Agriculture and Rural Development allow for the reduction of the number of tests to 2-3 in a single cycle for minor crops grown under cover (and since mushrooms are grown under controlled conditions, this can be considered under cover, despite the specific nature of their cultivation). However, the regulations do not specifically address the issue of minor crops grown under cover, where the substance is not yet approved for use in this area. Therefore, it is safer to conduct at least 6 efficacy tests in two cycles; then the situation will certainly be safe.
A link to the document from the Ministry's internal regulations regarding efficacy is below:
https://www.gov.pl/attachment/4abffb17-f78c-4d18-9775-f2c7dc992f1b

Pyriproxyfen itself is not new a substance in Poland, only the use in cultivated mushrooms is new. The current version of the Ministry's internal regulations regarding efficacy evaluation, updated on Feb. 26th 2026, which can be found at: https://www.gov.pl/web/rolnictwo/ustalenia-dotyczace-sporzadzania-oceny-lub-uwag-w-zakresie-srodkow-ochrony-roslin-przez-podmioty-upowaznione
allows to authorize uses in minor crops grown under cover based on 2-3 trials even in case of new active or new use of this active (Table in section 4 of the document, page 7).

Efficacy data
In summary:
Required number of efficacy trials: minimum 6, in 2 cycles
Based on the 2021 preliminary research report conducted by the Institute of Horticulture in Skierniewice, it was concluded that the most recommended doses, both in terms of residues and efficacy, are 0.1, 0.5, and 1.0 g a.i. m². The label-recommended dose should fall within this range. The most recommended dose appeared to be 0.5 g a.i./m².

The doses of 0.1, 0.5, and 1.0 g a.i./m² tested in the preliminary studies showed significant variance, therefore, in the registration efficacy studies, the range of these doses was narrowed, with differences no greater than 20-40%. This is defined in EPPO guidelines PP 1/225(1) Minimum Effective Dose. Therefore, the following doses were selected for the registration studies: 0.3 g a.i./m²; 0.5 g a.i./m² (as recommended on the label), and 0.7 g a.i./m².
Efficacy studies were conducted in accordance with EPPO guidelines, specifically including the requirements of EPPO guideline PP 1/167(2) Insects and mites on mushrooms.

The research showed that the tested preparation PYRIX 20 SL effectively inhibited the development of flies in mushroom cultivation.

Study Conclusions:
1. The tested Pyrix 20 SL and Pyrix 100 EC preparations demonstrated high effectiveness in controlling midges in mushroom cultivation.
2. Pyrix 20 SL and Pyrix 100 EC preparations had no negative impact on fruiting body yield.
3. Pyrix 20 SL and Pyrix 100 EC preparations did not demonstrate any phytotoxicity to the *Agaricus bisporus* mushroom.
Recommended label dose after efficacy trials : 15 ml/m² (0.3 g a.i./m²)

3.2.1.1 Information on the occurrence or possible occurrence of the development of resistance

The risk of resistance development cannot be considered negligible. Even though the GAP profile (single application per crop cycle) and the IPM context contribute favourably, the single-site mode of action with a documented history of resistance development and the enclosed, multigenerational pest population contribute unfavourably. Only provided that resistance-management measures are implemented, the overall resistance risk may be assessed as low to moderate. The analysis therefore supports the implementation of risk-mitigation measures. The following measures are proposed for inclusion in the dossier and, in abbreviated form, on the product label:

1) A maximum of one pyriproxyfen application per crop cycle (in accordance with GAP) – a key component of the anti-resistance strategy.
2) Rotation of modes of action between crop cycles – pyriproxyfen and other juvenile hormone mimics from IRAC Group 7 (e.g. methoprene, fenoxycarb) should not be used in consecutive crop cycles; alternate with products having a different mode of action.
3) Use of the full recommended dose and uniform application coverage – sublethal exposure may promote resistance selection.
4) Integration of non-chemical measures (hygiene, insect exclusion, substrate pasteurisation, biological control) as the foundation of pest management; pyriproxyfen should be used as one component of an integrated programme rather than as a stand-alone solution.
5) Monitoring of field performance and reporting of control failures.
6) Inclusion of resistance-management statements on the label consistent with IRAC recommendations and EPPO PP 1/213 (4).

3.2.2 Adverse effects on treated crops

Not found.

3.2.3 Observations on other undesirable or unintended side-effects

Not Applicable.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Validation of analytical method for determination of the active substance (pyriproxyfen) in the test item PYRIX 20SL was performed.

During the validation of the analytical method the following parameters: selectivity, linearity, accuracy
and precision (repeatability) were determined. Validation of analytical method was performed according
to experimental procedure SPB-FA/11 and Guideline SANCO/3030/99, rev. 5.
Results of the validation of the analytical method confirmed that this method is suitable for analysis the content of the active substance (pyriproxyfen) in the test item.

Noticed data gaps are:
The validation of a method for the determination of toluene in plant protection products should be presented. The method must be sufficiently sensitive to determine toluene in accordance with its possible content, calculated on the basis of the known content of the active substance in the PPP.

3.3.2 Analytical methods for residues

The Applicant submitted one method for analysis of residues of pyriproxyfen for the generation of pre-authorization data.
Analytical methods for <u>risk assessment</u> for plants:
1. Joanna Kicińska, 2025, Study code: 25/FSL/07

The method was shown to be highly selective, as it includes two parent-daughter ion mass transitions for Pyriproxyfen and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for analyte, interfering signal in control specimens were negligible, and thus the limit of detection (LOD) is 0.0025 mg/kg for mushrooms.

The levels of residues of Pyriproxyfen in mushrooms samples were calculated using linear calibration plots. The obtained results described in the report are fully reliable and reflect the raw data.

It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods SANTE/2020/12830, Rev.2 [2] and is applicable as enforcement and data generation method for determination of Pyriproxyfen in mushrooms matrices.

The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Analytical methods for <u>post-authorization control and monitoring purposes</u>:
Analytical methods for crops previously submitted for monitoring purposes and already EU evaluated in the DAR (November 2005) have been updated to meet current data requirements where appropriate (RAR, 2018). Some methods previously evaluated do not meet current guidance and are not accepted.
New method of Lindner, M., presented in RAR (2018) is available and evaluated as suitable post-registration.
This method is protected according to the List of information, tests and studies on which the RMS relies in its assessment for renewal of an active substance (August 2019) and cannot be used in this application to support the use of Pyrix 20 SL.

According to the RAR (2018):
There are published multi-methods available that have been shown to provide satisfactory accuracy and precision in determining residues of pyriproxyfen in foods. Of these, method EN 15662 (QuEChERS) is considered to be the most appropriate for current use by EU Reference Laboratories for MRL enforcement and it provides evidence that routine monitoring methods are compatible with those proposed by the Notifier.
European Standard method EN 15662 (Foods of plant origin – Determination of pesticide residues using LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE -

QuEChERS method) is widely used in EU Reference Laboratories (EURL) used for analysis of multiple pesticide residues. The QuEChERS (Quick, Easy, Cheap, Effective, Rugged and Safe) citrate multi residue method has been used for the analysis of pyriproxyfen in high water, dry, high acid and high oil crops. This method consists of liquid-liquid micro-extraction. This is followed by sample clean-up to remove unwanted matrix materials that interfere with chromatographic analysis. Samples are shaken with acetonitrile buffered with magnesium sulphate and then determined by LC-MS/MS. Dry and high acid commodities may be analysed using this method following the addition of water prior to extraction to weaken interactions of pesticides with the matrix to ensure adequate partitioning. The EN standard 15562 document indicates the applicability of the QuEChERS method for analysis of pyriproxyfen, summarising the observed recoveries following analysis using GC determination (mainly GC-MS) or LC determination (LC-MS/MS). This recovery data published on the EURL is summarised on the EURL website under the data pool (www.eurl-pesticides-datapool.eu/). This DataPool has been created by the EURL for Residues of Pesticides with the aim to provide pesticide residue analysts with a convenient and efficient access to information needed for proper decision-making in pesticide residue analysis. Within the data pool method validation data generated within the aim of method validation experiments from various laboratories using different methods of analysis is collated.
The existence of many reported and published validations of the established EU QuEChERS multi-method for pyriproxyfen with LOQ levels as low as 0.002 mg/kg reinforces the Notifier proposed monitoring methods and that the proposed residue definition for monitoring in food of plant origin can be enforced with an LOQ of at least 0.01 mg/kg for pyriproxyfen.

In the EURL database, for pyriproxyfen an abundant amount of data is included for QuEChERS. According to SANCO/825/00 rev 8.1 guidance, an ILV is not required if a published method is used.

The citrate buffered QuEChERS method is published in EN norm 15662:2008. The norm is currently being revised. The method validation provided under CA 4.2/03 employs a slightly different mobile phase than the published method, but considering the extraction technique is comparable, the RMS accepts that the QuEChERS method is acceptable for monitoring of the four major crop groups at an LOQ of 0.01 mg/kg. An additional ILV is not considered required.

Some methods previously evaluated in the DAR (November 2005) were fully re-evaluated in RAR (2018) and considered acceptable for monitoring of pyriproxyfen residues: in soil with an LOQ of 0.01 mg/kg and in air with an LOQ of 1 µg/m^3. The methods are not protected according to the List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the renewal of the active substance (August 2019) and can be used in this application to support the use of Pyrix 20 SL.

September 2026 (commenting period):
The applicant provided additional clarification regarding the data gap (Part B5).
Based on a comprehensive evaluation of the argumentation submitted by the Applicant in this Reporting Table, the zRMS has reviewed the regulatory justification regarding the requirement for analytical monitoring methods in matrices of animal origin for the active substance pyriproxyfen, in the context of the proposed specific use of the plant protection product Pyrix 20 SL exclusively in the cultivation of cultivated mushrooms.
There is no expectation of measurable residues in animal tissues, milk, or eggs resulting from this specific use. Therefore, in this particular and exceptional case of mushroom cultivation, the zRMS considers the arguments valid and supports the lifting of the data gap for analytical monitoring methods for pyriproxyfen in matrices of animal origin.
In this case, no additional analytical method or its ILV is required for matrices of animal origin.

Noticed data gaps are:
~~– an analytical method and its independent laboratory validation (ILV) for the determination of residues of pyriproxyfen in animal matrices are required and should be provided by the Applicant as a post-registration requirement;~~

- an analytical method and its independent laboratory validation (ILV) for the determination of residues of pyriproxyfen in water are required and should be provided by the Applicant as a post-registration requirement;
- an analytical method for the determination of residues of pyriproxyfen in body fluids and tissues is required and should be provided at the renewal of the active substance and/or re-evaluation of plant production product.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

Classification of the product for health derived by calculation in line Annex VI (Regulation 1272/2008)

Hazard class(es), categories	Eye irritation Hazard category 2
Hazard pictograms:	GHS07
Signal word:	Warning
Hazard statement(s):	H319: Causes serious eye irritation
Precautionary statement(s):	P264 Wash hands thoroughly after handling. P280 Wear eye protection/face protection. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention.
Additional labelling phrases:	To avoid risks to human and the environment, comply with the instructions for use. [EUH401]

Summary of evaluation of the acute toxicity including irritancy and skin sensitisation for product Pyrix 20 SL

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral (ATEmix Calculation)	= 4853 mg/kg bw	Yes	None	According to Reg 1272/2008, see Part C
LD_{50} dermal (ATEmix Calculation)	= 3184 mg/kg bw	Yes	None	According to Reg 1272/2008, see Part C
LC_{50} inhalation (ATEmix calculation)	= 23.14 mg/L air	Yes	None	According to Reg 1272/2008, see Part C
Skin irritation (additive calculation)	Non-irritant	Yes	None	According to Reg 1272/2008, see Part C
Eye irritation (additive calculation)	Irritant	Yes	H319: Causes serious eye irritation	According to Reg 1272/2008, see Part C
Skin sensitisation, (additive calculation)	Non-sensitising	Yes	None	According to Reg 1272/2008, see Part C
Supplementary studies for combinations of plant protection products	No data – not required	--	--	--

3.4.2 Operator exposure

In the EFSA calculator, the critical use is expressed as bare arable land.
As the downward spray application is automatized (remotely controlled by computer) with nobody present in the mushroom cultivation room during the application, operator exposure is only assessed during the mixing/loading phase.
The potential total systemic exposure of the operator, dressed in work wear covering the body, arms and legs, at mixing and loading, with additional gloves corresponds to 9.0 % of the AAOEL for Pyriproxyfen, regarding the critical use in mushroom.
The potential total systemic exposure of the operator, dressed in work wear covering the body, arms and legs, at mixing and loading, with additional gloves corresponds to 8.2 % of the AOEL for Pyriproxyfen, regarding the critical use in mushroom.

There is no unacceptable risk for operator wearing workwear and gloves during mixing and loading regarding the critical use in mushroom.

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

3.4.3 Worker exposure

The potential total systemic exposure of the worker, corresponds to 0.6% of the AOEL for regarding the critical use in mushroom.

Worker exposure when contact with soil is possible during their activities (e.g. manual mushroom harvest) is acceptable without work clothes or PPE/RPE.

As good agricultural practice, wearing protective gloves is recommended when contact with soil is possible during worker activities.

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

3.4.4 Bystander and resident exposure

No exposure of resident or bystander is expected considering the product will be applied automatically in completely closed isolated buildings, in controlled cultivation conditions preventing for potential air contamination and thus transfer from the mushroom house to the outside atmosphere is impossible.

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Pyriproxyfen will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

3.5 Residues and consumer exposure (Part B, Section 7)

3.5.1 Residues

Residue Definitions (EFSA 2009, 2019; Reg EU 2023/1753):
Monitoring (Mo): Pyriproxyfen
Risk Assessment (RA): Pyriproxyfen

Mushrooms
Mushrooms are the minor crop in northern Europe (SANTE/2019/12752). A minimum of four trials

are required.

New residue study was submitted in the framework of this application.

Sufficient trials on mushrooms (3 trials) conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 3000 g a.s. /ha, BBCH: over-growth of cover by mushroom mycelium, spraying two days after applying a torf cover, indoor.

In the treated mushrooms residue levels of pyriproxyfen at harvest were never above the LOD (<0.0025 mg/kg).

In accordance with SANTE/2019/12752, three trials are considered sufficient for minor crops in a <LOQ situation; therefore, the available data set is deemed adequate to support the proposed use on mushrooms (cultivated fungi).

Available results show that the in force MRL of pyriproxyfen on fungi/mushrooms of 0.01* mg/kg (Reg EU 2023/1753) will not be exceeded.
The trials are supported by validated analytical method.
The study on the magnitude of residues is valid with regard to storage stability on tomatoes, but additional storage data for mushrooms are needed.

The proposed use on mushrooms is considered acceptable.

As residues of pyriproxyfen do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Uses under consideration are not relevant in terms of animal feed.

Crops under evaluation (mushrooms) are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required although data on metabolism of pyriproxyfen in rotational crops are available.

The proposed use of pyriproxyfen in the formulation Pyrix 20 SL do not represent unacceptable acute and chronic risks for the consumer.

Noticed data gaps are:

- Studies on the storage stability of pyriproxyfen in mushrooms under frozen conditions are required and should be provided as a post-registration requirement.

3.5.2 Consumer exposure

TMDI calculation was performed using the in-force MRLs (Regulation (EU) 2023/1753) for all crops and animal commodities. An acute consumer risk assessment was performed only for the crop under consideration, based on the in-force MRL.
The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) 2023/1753 led to a utilisation of the ADI of 17 % with the NL toddler being the population group with the highest value. The intended use will not result in a consumer chronic exposure exceeding the ADI for pyriproxyfen.
An acute consumer risk assessment was performed only for the crop under consideration, based on the MRL of mushrooms. The IESTI is at 0 % of the ARfD for the consumption of mushrooms by children and by adults.
The chronic and the short-term intakes of pyriproxyfen residues are unlikely to present a public health concern.
The intended use of Pyrix 20 SL is accepted.

3.6 Environmental fate and behaviour (Part B, Section 8)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment (soil, water, surface water, ground water, air) and animals.

3.6.1 Predicted environmental concentrations in soil (PEC_{soil})

Since the application of the product will be conducted in a closed buildings no soil contamination is expected. In accordance with the *EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments* (EFSA Journal 2014;12(3):361, Table 1, page 5) a soil exposure assessment for the application in closed buildings is considered not relevant.

However, according to the information provided by the Applicant, the spent mushroom substrate will be disposed of as waste and subsequently used as compost. According to polish Waste Act of 14 December 2012, and in accordance with the European Waste Catalogue (EWC), spent mushroom substrate is classified as agricultural waste under EWC code 02 01 99 "wastes not otherwise specified".
The use of the spent mushroom substrate as compost may result in indirect exposure of soil to residues of the active substance and its metabolites. Nevertheless, the pyripoxyfen and its relevant soils metabolites are not considered to be persistent in soil (the DT_{50} values are below 120 days, and DT_{90} values are below 365 days). Therefore, no further assessment of soil exposure is required for the substrate further used as a compost.

3.6.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Since the application of the product will be conducted in a closed buildings no ground water contamination is expected. In accordance with the *EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments* (EFSA Journal 2014;12(3):361, Table 1, page 5) the ground water exposure assessment for the application in closed buildings is considered not relevant.

However, according to the information provided by the Applicant, the spent mushroom substrate will be disposed of as a waste and subsequently used as compost. According to polish Waste Act of 14 December 2012, and in accordance with the European Waste Catalogue (EWC), spent mushroom substrate is classified as agricultural waste under EWC code 02 01 99 "wastes not otherwise specified".
The use of the spent mushroom substrate as compost may result in indirect exposure of ground water to residues of the active substance and its metabolites. Nevertheless, the pyripoxyfen and its relevant soils metabolites are not considered to be persistent in soil (the DT_{50} values are below 120 days, and DT_{90} values are below 365 days). Therefore, no further assessment of ground water exposure is required for the substrate further used as a compost, and leaching of pyriproxyfen or its metabolites is considered insignificant.

According to polish requirements, wastewater after cleaning the chambers were the product has been used must be collected and disposed of appropriately, to prevent that no residues can enter the drainage water and/or sewage system. The wastewater shall be collected and transferred to an entity authorised to collect and manage hazardous waste, in accordance with applicable national waste regulation.

3.6.3 Predicted environmental concentrations in surface water (PEC_{sw})

Since the application of the product will be conducted in a closed buildings no surface water contamination is expected. In accordance with the *EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments* (EFSA Journal 2014;12(3):361, Table 1, page 5) the surface water exposure assessment for the application in closed buildings is considered not relevant.

According to polish requirements, wastewater after cleaning the chambers were the product has been used must be collected and disposed of appropriately, to prevent that no residues can enter the drainage water and/or the sewage system. The wastewater shall be collected and transferred to an entity authorised to collect and manage hazardous waste, in accordance with applicable national waste regulation.

3.6.4 Predicted environmental concentrations in air (PEC_{air})

Contamination of the atmosphere with pyriproxyfen from the intended uses of Pyrix 20SL is considered to be negligible, and the exposure of adjacent surface waters by the active substance pyriproxyfen due to volatilization with subsequent deposition not need to be considered.

3.7 Ecotoxicology (Part B, Section 9)

The specificity of spraying mushrooms (classified as Closed building) excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants.
Therefore there is no need to perform a risk assessment for all group non-target organism according to rec-commendation given in: ,,EFSA Supporting publication 2015:EN-924:,,Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, Table 2, category permanent greenhouse) and in EFSA Journal 2014;12(3):3615: ,,EFSA Guidance Document on clustering and ranking of emissions of actives sub-stances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments''.

3.7.1 Effects on terrestrial vertebrates

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to birds and mam-mals is expected and therefore, no risk assessment, including risk from drinking water exposure and from secondary poising is required for birds and mammals. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2): EFSA Supporting publication 2015:EN-924; ,,Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" (Table 2, category permanent greenhouse).

Therefore, overall, an acceptable risk to birds and mammals is concluded for all intended use of Pyrix 20 SL.

3.7.2 Effects on aquatic species

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to aquatic organism is expected and therefore, no risk assessment is required for aquatic organism. This is in line with the recom-mendations given in the EFSA Technical Report (2015, Table 2) and EFSA Journal 2014;12(3):3615 (Table 1).

Therefore, overall, an acceptable risk to aquatic organism concluded for all intended use of Pyrix 20 SL.

3.7.3 Effects on bees

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to bees is expected and therefore, no acute and chronic risk assessment, is required for aquatic organism. This is in line with the recommendations of the EFSA Technical Report (2015, Table 2).

Therefore, overall, an acceptable risk to bees is concluded for all intended use of Pyrix 20 SL.

3.7.4 Effects on other arthropod species other than bees

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to non-target arthropods is expected and therefore, risk assessment in-field or off-field, is required for NTA. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2).
Therefore, overall, an acceptable risk to non-target arthropods is concluded for all intended use of Pyrix 20 SL.

3.7.5 Effects on soil organisms

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to non-target soil meso-and macrofauna is expected and therefore, no risk assessment, is required for these species. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2) and EFSA Journal 2014;12(3):3615 (Table 1).

Therefore, overall, an acceptable risk to non-target soil meso-and macrofauna concluded for all intended use of Pyrix 20 SL.

3.7.6 Effects on non-target terrestrial plants

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to non-target plants is expected and therefore, no risk assessment, is required. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2).

Therefore, overall, an acceptable risk to NTTP concluded for all intended use of Pyrix 20 SL.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to other terrestrial organism is expected and therefore, no risk assessment, on other terrestrial organism. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2).

Therefore, overall, an acceptable risk on other terrestrial organism to concluded for all intended use of Pyrix 20 SL

3.8 Relevance of metabolites (Part B, Section 10)

Not required.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Pyrix 20 SL contains active substance pyriproxyfen use in protecting mushrooms against *Sciaridae* is not suitable for substitution because there is no insecticides approved for protective mushrooms against *Sciaridae* in EU and in Poland. There are no other chemical products in an alternative mode of action.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Noticed data gaps are:

Metabolism and residue:

- studies on the storage stability of pyriproxyfen in mushrooms under frozen conditions are required and should be provided as a post-registration requirement.

Analytical methods

- validation of a method for the determination of toluene in plant protection products should be presented. The method must be sufficiently sensitive to determine toluene in accordance with its possible content, calculated on the basis of the known content of the active substance in the PPP.
- ~~an analytical method and its independent laboratory validation (ILV) for the determination of residues of pyriproxyfen in animal matrices are required and should be provided by the Applicant as a post-registration requirement;~~
- an analytical method and its independent laboratory validation (ILV) for the determination of residues of pyriproxyfen in water are required and should be provided by the Applicant as a post-registration requirement;
- an analytical method for the determination of residues of pyriproxyfen in body fluids and tissues is required and should be provided at the renewal of the active substance and/or re-evaluation of plant production product.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, toksykologii i istotności toksykologicznej metabolitów, pozostałości, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub ~~przekreśleniem~~ i jasno-szarą czcionką (fragmenty usunięte).
Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2-letnie badania stabilności są w toku. Można uznać warunkowo 2 letni okres przechowywania na podstawie wyników zaakceptowanych badań przyspieszonego starzenia (2 tygodnie w temperaturze 54ºC) oraz wyników po 12 miesiącach przechowywania środka ochrony roślin przechowywanego w opakowaniach wykonanych z HDPE/PA. Na podstawie zapisów wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 05.01.2026 dla środków ochrony roślin (formulacja SL) możliwa jest ekstrapolacja wyników stabilności po miedzy każdym typem opakowań z tworzyw sztucznych. W związku z powyższym można zaakceptować wszystkie proponowane opakowania, wymienione w punkcie 4.1 Sekcji 1,2,4.
3. Brak uwag do zaproponowanych w etykiecie zapisów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin.
4. Brak uwag do nazwy grupy chemicznej, do której przyporządkowano substancje czynną, zaktualizowano zapis dotyczące zawartości (gęstość zgodnie z punktem 2.6.2 Sekcji 1,2,4: 1.045 g/cm^3).
5. Zgodnie z informacjami zawartymi w tabeli 2-1, w punkcie 2.9.1 i 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Zmodyfikowano treść rozdziału OPIS DZIAŁANIA dodając definicję biologicznej aktywności s.a., informację o jej przynależności do grupy w klasyfikacji IRAC, oraz korygując informacje o biologicznych skutkach działania na owada.
2. Wprowadzono do etykiety rozdział STRATEGIA ZARZĄDZANIA ODPORNOŚCIĄ.

Sekcja metody analityczne:

1. Brak uwag do etykiety w zakresie metod.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej klasyfikacji zagrożeń odpowiednie zwroty zmodyfikowano zgodnie z klasyfikacją zagrożeń CLP/GHS, patrz dRR B6 (Tabela 6.3-1) oraz Część C s.20
2. W części dotyczącej środków ostrożności dla osób stosujących środek, pracowników oraz osób postronnych odpowiedni zwrot zmodyfikowano zgodnie z wynikiem szacowania NDE oraz klasyfikacji CLP (patrz wymagania Harmonizacje Min. Rol. Toksykologia Aktualizacja 29.12.2025r.)
3. W części dotyczącej pierwszej pomocy odpowiednie zwroty zweryfikowano zgodnie z klasyfikacją zagrożeń.

Sekcja pozostałości

1. Brak uwag do etykiety w zakresie sekcji pozostałości.

Sekcja los i zachowanie w środowisku:

1. Proponuje się wstawienie poniższego zdania do etykiety, jednak finalną decyzje pozostawiamy Ministerstwu Rolnictwa i Rozwoju Wsi: Ścieki powstające podczas czyszczenia pomieszczeń, w których stosowano środek zawierający piryproksyfen, należy zebrać i przekazać podmiotowi uprawnionemu do odbioru i gospodarowania odpadami niebezpiecznymi, zgodnie z obowiązującymi krajowymi przepisami dotyczącymi gospodarki odpadami.

Sekcja ekotoksykologia:

1. Wprowadzono zmiany do klasyfikacji środka.

Załącznik do zezwolenia MRiRW nr ……. z dnia……. r.

Posiadacz zezwolenia:
Agrofarm Sp. z o.o., ul. Dzika 4A/58; 00-194 Warszawa, tel.:/fax +48 22 810 11 37; e-mail: biuro@agrofarm.pl

Podmiot wprowadzający środek ochrony roślin na terytorium RP:
Agrofarm Sp. z o.o., ul. Dzika 4A/58; 00-194 Warszawa, tel.:/fax +48 22 810 11 37; e-mail: biuro@agrofarm.pl

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin:
Agropak Sp. J. Brzeziński i Wspólnicy, ul. Karola Darwina 1d, 43-603 Jaworzno
Schirm GmbH; Geschwister-Scholl-Strasse 127; 39218 Schönebeck (Elbe), Germany

PYRIX 20 SL

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
piryproksyfen (związek z grupy pochodnych eterowych pirydyny) - 20 g/l (1,91%)

Składniki stwarzające zagrożenie: propylene glycol phenyl ether

Zezwolenie MRiRW nr ……. z dnia…….. r. na wprowadzanie do obrotu środka ochrony roślin PYRIX 20 SL



GHS07



GHS 09

Uwaga

H410 - Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
H319 - Działa drażniąco na oczy

EUH 401 - W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

P280 - Stosować ~~rękawice ochronne~~ ochronę oczu/ochronę twarzy.
P264 Dokładnie umyć dłonie po użyciu.
P305 + P351 + P338 W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Kontynuować płukanie..
P337 + P313 W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P273 - Unikać uwolnienia do środowiska.
P391 - Zebrać wyciek.
P501 - Zawartość/pojemnik usuwać zgodnie z obowiązującym prawem. ~~Zawartość/pojemnik usuwać , przekazać do uprawnionych punktów utylizacji~~

OPIS DZIAŁANIA

PYRIX 20 SL jest środkiem owadobójczym w formie koncentratu rozpuszczalnego w wodzie (SL), o działaniu kontaktowym, i żołądkowym do zwalczania muchówek (*Sciaridae*) w uprawie pieczarek.
~~Środek~~ Substancja aktywna preparatu: piryproksyfen, należy do grupy 7C w klasyfikacji IRAC. Działa jako mimetyk ~~analog~~ hormonu juwenilnego, zakłóca równowagę hormonalną u owadów powodując zaburzenie procesów rozwojowych. Działa głównie w późnych stadiach larwalnych, ~~późnej fazie larwalnej~~ hamując proces ~~linienia i~~ przeobrażania larw do stadium owada dorosłego ~~kolejnych stadiów rozwojowych~~, co prowadzi do ich zamierania. Środek przeznaczony do stosowania przy użyciu opryskiwaczy ręcznych.

STOSOWANIE ŚRODKA

Pieczarka
muchówki (*Sciaridae*)- owady dorosłe
Maksymalna/zalecana dawka dla jednorazowego zastosowania:
15 ml środka na 1 m^2 uprawy stosując 1L wody.

Termin stosowania środka:
Faza rozwojowa rośliny uprawnej podczas zabiegu w skali BBCH: przerost okrywy przez grzybnię pieczarki.
Opryskiwać półki do 2 dni po nałożeniu okrywy. Szczególnie dokładnie potraktować brzeżne części półek.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA

*Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (**okres prewencji**):*
Nie dotyczy.

*Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (**okres karencji**):*
Pieczarka – nie dotyczy.

*Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami **(okres karencji dla pasz):***
Nie dotyczy.

Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić rośliny uprawiane następczo:
Nie dotyczy

STRATEGIA ZARZĄDZANIA ODPORNOŚCIĄ:
W celu zminimalizowania ryzyka wyłonienia odporności w populacji agrofaga zaleca się co następuje:

- Stosowanie maksymalnie jednej aplikacji środka w cyklu uprawowym,
- W kolejnych cyklach uprawowych – przemienne z piryproksyfenem stosowanie środków o innych mechanizmach działania – o ile są dostępne. Piriproksyfenu ani innych substancji z grupy 7 IRAC, naśladujących działanie hormonu juwenilnego (np. metoprenu, fenoksykarbu) nie należy stosować w kolejnych cyklach uprawowych,
- Stosowanie pełnej zalecanej dawki i równomierne pokrycie substratu cieczą podczas aplikacji – narażenie szkodnika na niepełną dawkę może sprzyjać selekcji odporności,
- Włączenie do programu ochrony metod niechemicznych (higiena, zapobieganie przedostawaniu się owadów, pasteryzacja podłoża, zwalczanie biologiczne); piriproksyfen powinien być

stosowany jako jeden z elementów programu zintegrowanego, lecz nie jako samodzielne i jedyne rozwiązanie,
– Monitorowanie skuteczności na terenie obiektu i zgłaszanie niepowodzeń w zwalczaniu szkodników.

SPORZĄDZANIE CIECZY UŻYTKOWEJ wyłącznie w pomieszczeniach zamkniętych

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość preparatu wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem) i uzupełnić wodą do potrzebnej ilości. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać. Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Opryskiwać z włączonym mieszadłem.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia, tj.:
– po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
– unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
– unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek:
Nie jeść, nie pić ani nie palić podczas używania produktu.
Stosować rękawice ochronne, ochronę oczu i twarzy, odzież ochronną, odpowiednie obuwie (np. kalosze) oraz ochronę dróg oddechowych zabezpieczającą przed oddziaływaniem środka ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.
Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu
Dokładnie umyć ręce po użyciu.

Środki ostrożności związane z ochroną środowiska naturalnego:
Ścieki powstające podczas czyszczenia pomieszczeń, w których stosowano środek zawierający piryproksyfen, należy zebrać i przekazać podmiotowi uprawnionemu do odbioru i gospodarowania odpadami niebezpiecznymi, zgodnie z obowiązującymi krajowymi przepisami dotyczącymi gospodarki odpadami.
Nie zanieczyszczać wód i gleby środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych.
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.
Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W przypadku kontaktu ze skórą: umyć dużą ilością wody
W przypadku połknięcia: natychmiast skontaktować się z ośrodkiem zatruć/lekarzem.
Nie wywoływać wymiotów.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

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.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

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

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.4.1	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						office and wasn't used in the assessment of another PPP	
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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.5.1	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.5.2	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						used in the assessment of another PPP	
KCP 2.6.1	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.6.2	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.7.1	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						another PPP	
KCP 2.7.5	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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.7.2	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.7.3	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.5	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.8.2	M.Legan, MWłodarczyk/ 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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 2.11	M.Legan, MWłodarczyk/	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	N	Y	Data/study report never	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	SORBOLAB Research Laboratory LLC ,Poznań, Poland		and after stability tests . Study code :0012/0004/FA GLP- Yes Unpublished			submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	
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	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.

PART B Section 3 Efficacy Data and Information

Data point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
EFFICACY 6.2 6.4.2	Szumigaj-Tarnowska J.	2022	Ocena skuteczności biologicznej preparatów Pyrix 20 SL i Pyrix 100 EC (piryproksyfen) w zwalczaniu muchówek (Sciaridae) w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL and Pyrix 100 EC (pyriproxyfen) in the control of flies (Sciaridae) in the mushrooms cultivation *Agaricus bisporus.* Trial No. ZBZNBH/12/2022/1/I Institute of Horticulture – National Research Institute	N	Y	Data/study report never submitted before to Poland (or other country) registration office	Agrofarm Sp. z o.o.

			GEP – yes Unpublished				
EFFICACY 6.2 6.4.2	Szumigaj-Tarnowska J.	2022	Ocena skuteczności biologicznej preparatów Pyrix 20 SL i Pyrix 100 EC (piryproksyfen) w zwalczaniu muchówek (Sciaridae) w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL and Pyrix 100 EC (pyriproxyfen) in the control of flies (Sciaridae) in the mushrooms cultivation *Agaricus bisporus.* Trial No. ZBZNBH/12/2022/1/II Institute of Horticulture – National Research Institute GEP – yes Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office	Agrofarm Sp. z o.o.
EFFICACY 6.2 6.4.2	Szumigaj-Tarnowska J.	2023	Ocena skuteczności biologicznej preparatów Pyrix 20 SL (piryproksyfen) w zwalczaniu muchówek w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL (pyriproxyfen) in the control of flies in the mushroom cultivation *Agaricus bisporus*. Trial No. ZBZNBH/4/2023/1/I Seria 1; Seria 2 Institute of Horticulture – National Research Institute GEP – yes Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office	Agrofarm Sp. z o.o.
EFFICACY 6.2 6.4.2	Szumigaj-Tarnowska J.	2023	Ocena skuteczności biologicznej preparatów Pyrix 20 SL (piryproksyfen) w zwalczaniu muchówek w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL (pyriproxyfen) in the control of flies in the mushroom cultivation *Agaricus bisporus*. Trial No. ZBZNBH/4/2023/2/I Institute of Horticulture – National Research Institute GEP – yes Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office	Agrofarm Sp. z o.o.
EFFICACY 6.2 6.4.2	Szumigaj-Tarnowska J.	2024	Ocena skuteczności biologicznej preparatów Pyrix 20 SL (piryproksyfen) w zwalczaniu muchówek w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL (pyriproxyfen) in the control of flies in the mushroom cultivation *Agaricus bisporus*. Trial No. ZBZNBH/4/2024/1/I Seria 1; Seria 2 Institute of Horticulture – National Research Institute GEP – yes Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office	Agrofarm Sp. z o.o.

PART B Section 5 Analytical Methods

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1	Agrofarm	March 2025	Analytical method for determining the content of pyriproxyfen in the product Pyrix 20 SL. Agrofarm A310322. (Procedure for determining pyriproxyfen in the product) source : Agrofarm Sp. z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 5.1.1	B.Ciorga, M.Włodarczyk	May 2025	Final report. Validation of analytical method for the determination of active substance (pyriproxyfen) content in the test item PYRIX 20SL Test item :PYRIX 20 SL Study code :0012/0003/FA source: SORBOLAB Research Laboratory LLC GLP: YES Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 5.1.2	Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/	2025	Expert Statement on the Classification of Indoor Mushroom Cultivation GLP- NO Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						assessment of another PPP	
KCP 5.2	Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/	2025	Expert Statement on the Classification of Indoor Mushroom Cultivation GLP- NO Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 5.2	Damian Gorczyca, PhD B.Stepien K.Baranowski N.Witaszak LymeLab Pharma sp. z o. o. sp. k	2025	**STUDY TITLE -FIELD PART:** Magnitude of the residue of pyriproxyfen (CAS 95737-68-1) in Mushrooms *Agaricus bisporus* (Raw Agricultural Commodity - RAC) grown in closed buildings conditions after one application of a formulated product of PYRIX 20 SL - one harvest and two decline curve trials in Northern Europe. Poland – 2025 Study number: LLP25-2 Harvest trial number: LLP25-2-01 Decline trial number: LLP25-2-02 Decline trial number: LLP25-2-03 Test Site : LymeLab Pharma sp. z o. o. sp. k. ;Cebulki 19 ; 13-124 Kozłowo, POLAND; Test Facility : LymeLab Pharma sp. z o. o. sp. k. ;Trylogii 2/16 ; 01-982 Warsaw, POLAND GAP-YES Unbuplished	N	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
KCP 5.2	J.Kicinska; A.Miszczak, Dr Food Safety Laboratory.The	2025	**STUDY TITLE - ANALITYCAL PART:** **1.**Determination of the residue of pyriproxyfen in mushrooms after application of "PYRIX 20 SL" in northen Europe- Poland 2025. Study code: 25/FSL/07 Year: 2025	N	Y	Data/study report never submitted before to Poland (or	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	National Institute of Horticultural Research -Poland		Test Facility: Food Safety Laboratory.The National Institute of Horticultural Research; 13B Pomologiczna Street; 96-100 Skierniewice Poland GLP- YES Unpublished			other country) registration office and wasn't used in the assessment of another PPP	
KCP 5.2	J.Kicinska; A.Miszczak, Dr Food Safety Laboratory.The National Institute of Horticultural Research -Poland	2025	**STUDY TITLE - ANALITYCAL PART:** **2.**Determination of the residue of pyriproxyfen in mushrooms after application of "PYRIX 20 SL" in northen Europe- Poland 2025. Study code: 25/FSL/16 Year: 2025 Test Facility: Food Safety Laboratory.The National Institute of Horticultural Research; 13B Pomologiczna Street; 96-100 Skierniewice Poland GLP- YES Unpublished	N	Y	Data/study report never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.

PART Section 6 Mammalian Toxicology

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
All KCP 6.3	Australian National Registration Authority For Agricultural and Veterinary Chemicals	1995	Public Release Summary – PYRIRPOXYFEN In the product Sumilarv Insect Growth Regulator – APVMA 363 1995	N	N	-	APVMA Public Release Summary

PART B Section 7 Metabolism and Residues

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
7.2.3 A.2.1.3.1	Damian Gorczyca, PhD B.Stepien K.Baranowski N.Witaszak LymeLab Pharma sp. z o. o. sp. k	2025	STUDY TITLE -FIELD PART: Magnitude of the residue of pyriproxyfen (CAS 95737-68-1) in Mushrooms Agaricus bisporus (Raw Agricultural Commodity - RAC) grown in closed buildings conditions after one application of a formulated product of PYRIX 20 SL - one harvest and two decline curve trials in Northern Europe. Poland – 2025 Study number: LLP25-2 Harvest trial number: LLP25-2-01 Decline trial number: LLP25-2-02 Decline trial number: LLP25-2-03 Test Site : LymeLab Pharma sp. z o. o. sp. k. ;Cebulki 19 ; 13-124 Kozłowo, POLAND; Test Facility : LymeLab Pharma sp. z o. o. sp. k. ;Trylogii 2/16 ; 01-982 Warsaw, POLAND GAP-YES Unbuplished	N	Y	Data/study report never submitted before to Poland(or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.
7.2.3 A.2.1.3.1	J.Kicinska; A.Miszczak, Dr Food Safety Laboratory.The National Institute of	2025	STUDY TITLE - ANALITYCAL PART: 1.Determination of the residue of pyriproxyfen in mushrooms after application of “PYRIX 20 SL” in northen Europe- Poland 2025. Study code: 25/FSL/07 Year: 2025 Test Facility: Food Safety Laboratory.The National Institute of Horticultural	N	Y	Data/study report never submitted before to Poland (or other country)	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	Horticultural Research -Poland		Research; 13B Pomologiczna Street; 96-100 Skierniewice Poland GLP- YES Unpublished			registration office and wasn't used in the assessment of another PPP	
7.2.3 A.2.1.3.1	J.Kicinska; A.Miszczak, Dr Food Safety Laboratory.The National Institute of Horticultural Research -Poland	2025	STUDY TITLE - ANALITYCAL PART: 2.Determination of the residue of pyriproxyfen in mushrooms after application of "PYRIX 20 SL" in northen Europe- Poland 2025. Study code: 25/FSL/16 Year: 2025 Test Facility: Food Safety Laboratory.The National Institute of Horticultural Research; 13B Pomologiczna Street; 96-100 Skierniewice Poland GLP- YES Unpublished	N	Y	Data/study report never submitted before to Poland(or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.

Part B Section 8 Environmental Fate

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
All KCP 8	Marielle Fortin-McCuaig / EUROFINS	2025	Expert Statement on the Classification of Indoor Mushroom Cultivation EUROFINS Agroscience regulatory GLP-non Unpublished	N	Y	Data never submitted before to Poland(or other country) registration office and wasn't used in the	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						assessment of another PPP	

Part B Section 9 Ecotoxicology

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
All KCP 9	Marielle Fortin-McCuaig / EUROFINS	2025	Expert Statement on the Classification of Indoor Mushroom Cultivation EUROFINS Agroscience regulatory GLP-non Unpublished	N	Y	Data never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.

Part B Section 10 Assessment of the relevance of metabolites in groundwater

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
All KCP 10	Marielle Fortin-McCuaig / EUROFINS	2025	Expert Statement on the Classification of Indoor Mushroom Cultivation EUROFINS Agroscience regulatory GLP-non Unpublished	N	Y	Data never submitted before to Poland (or other country) registration office and wasn't used in the assessment of another PPP	Agrofarm Sp. z o.o.

PART C Confidential Information

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	Confidential request Y/N	Justification if data protection is claimed	Owner
All dokument Part C	Agrofarm	2025	Request for confidentiality in accordance with Article 63 of Regulation (EU) No. 1107/2009 in Polish.	-	Y	trade secret	Agrofarm Sp. z o.o.
1.1.2	Tagros Chemicals India Private Limited	2025	Letter ofSupply and data access to Pyriproxyfen active cocncentrate Issued to Agrofarm Sp. z o.o.	-	Y	trade secret Data never submitted before to Poland or other country registration office and wasn't used in the assess-ment of another PPP	Agrofarm Sp. z o.o.
1.1.2 1.1.3	Olivier Guelton Head of Unit Authorizations	2025	Evaluation of the equivalence of a new source of the active substance pyriproxyfen-approval at European level. OUR REF: 41.500/22/ Federal Public Service. Healt, Food Chain Safety and Environment. DG – Animals, Plants and Food Plant Protection Products and Fertilisers. Brussels ,Belgium Uupublished	-	N ~~Y~~	~~trade secret~~ Information available upon submission of an access request	Agrofarm Sp. z o.o.
1.1.3	Tagros Chemicals India Private Limited	2025	PRODUCT SPECIFICATION PYRIPROXYFEN TECHNICAL	-	Y	trade secret Data never submitted before to Poland or other country registration office and wasn't used in the assess-	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	Confidential request Y/N	Justification if data protection is claimed	Owner
						ment of another PPP	
1.2.1 1.2.3	Agrofarm	2025	Pyrix 20 SL - Manufacturing Process Description	-	Y	trade secret Data never submitted before to Poland or other country registration office and wasn't used in the assess-ment of another PPP	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
All KCP 6.3	Australian National Registration Authority For Agricultural and Veterinary	1995	Public Release Summary – PYRIRPOXYFEN In the product Sumilarv Insect Growth Regulator – APVMA 363 1995	-	-	-	Public Release Summary
All KCP 6.3	EFSA	2019	Peer review of the pesticide risk assessment of the active substance pyriproxyfen. EFSA Journal 2019;17(7):5732 Published	-	-	-	EFSA Public

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
All KCP 6.3	EFSA	2019	Peer review of the pesticide risk assessment of the active substance pyriproxyfen. EFSA Journal 2019;17(7):5732 Published	-	-	-	EFSA Public

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

APPENDIX 5 DATA PROTECTION REQUEST according Article 59 of Regulation (EU) No 1107/2009 in Polish

Agrofarm attaches a separate data protection request in Polish.