Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATION

(submitted by the competent autority)

FLY IN

Product type 19

Saccharomyces cerevisiae (yeast) and powdered egg as included in the Annex I of Regulation (EU) No 582/2012]

Case Number in R4BP: BC-SY066617-89

Competent Authority: IT

Date: August 2022

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Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page

1 Conclusion

FLY IN is a water soluble powder formulation (SP) biocidal product containing *Saccharomyces cerevisiae* (yeast) and powdered egg as active substances. The product is used as an attractant (PT19) by professional and non-professional (general public) for the control of flies.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the uses as an attractant (PT19) by professional and non-professional (general public), as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended uses of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, the biocidal product does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substances *Saccharomyces cerevisiae* (yeast) and powdered egg are listed in Annex I of Regulation (EU) 528/2012 and satisfy the restriction excluding *Saccharomyces cerevisiae* (yeast) and powdered food that are not food or feed;
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008[1] is not necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Noneless, some basic informance is provided for the determination of the concentration of the active substances is available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against flies for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A risk assessment for human health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Dietary risk assessment

A risk assessment for dietary is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Risk assessment for animal health

A risk assessment for animal health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Risk assessment for the environment

A risk assessment fot the environment is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Post-authorisation conditions

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2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type	PT19
Type of formulation	SP – Water soluble powder

2.2 Uses

Two uses have been proposed by the applicant.

Use # 1
The product "Fly in – Fly trap" is marketed in a bag commercial packaging that only needs to fill water till the "fill line". This bag has already the powder formulation inside and the capacity of the water that must be filled. No contact with the powder is needed.

Use # 2
The product should be dissolved in water and poured into a trap. The product "Fly in - Exclusive formulation for traps", is marketed in bag commercial packaging that requires to extract the powder formulation by spoon to another bag where is diluted with water and used as trap.

For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below.

Table 2.2 Overview of uses of the biocidal product

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (eCA/ refMS)[8]	Comment (eCA/refMS)[9]
# 1	Fly in – Fly trap to fill with water	PT19	Flies (*Musca domestica* and *Stomoxys calcitrans*)	The trap should be filled with water	30g of product per litre of water	Professional and non professional	A	-
# 2	Fly In - Exclusive Formulation for traps			The product should be dissolved in water and poured into the trap	30g of product per litre of water		A	-

[1] Use number (as applied for), as indicated in the SPC
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for the specific use
[6] Min-max. application rate of the product for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

[9] If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Identity and composition

The determination whether the identity and composition of the biocidal product are identical or not identical to the identity and composition of the products evaluated in connection with the inclusion of the active substances in Annex I of Regulation (EU) No 528/2012, is not applicable.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substances

Main constituent(s)	
Common name	Yeast
Chemical name	Saccharomyces cerevisia
EC number	Not available
CAS number	68876-77-7
Index number in Annex VI of CLP	Not available
Minimum purity / content	Not applicable
Structural formula	Not applicable

Main constituent(s)	
Common name	Powdered egg
Chemical name	Not available
EC number	Not available
CAS number	Not available
Index number in Annex VI of CLP	Not available
Minimum purity / content	Not applicable

Structural formula	Not applicable

2.5 Information on the source(s) of the active substance(s)

The information on the sources of the active substances is not applicable.

2.6 Candidate(s) for substitution

Not applicable.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The product does not show any alert for endocrine disruptors.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Not classified	-
Hazard Pictograms	None	-
Signal word(s)	None	-
Hazard statements	None	-
Precautionary statements*	None	P102-Keep out of reach of children
Supplemental hazard statements	None	
Notes	-	

***P-statements that are excluded based on the risk assessment or the intended use of the product[2], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[2] Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

2.9 Letter of access

No Letter of Access to the active substances or to the product have been submitted.

2.10 Data submitted in relation to product authorisation

No new data on the active substances have been submitted.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging[1]	Size/volume of the packaging[2]	Material of the packaging[3]	Type and material of closure(s)	Intended user[4]	Compatibility of the product with the proposed packaging materials (Yes/No)
Bag	30 g / 50 g / 100 g / 125 g	Aluminum foil	-	Professional and non-professional	Yes
Jars	250 g / 1 kg / 3 kg	Polyethylene	-	Professional and non-professional	Yes
Bag	125 g / 150 g	Aluminium plastic	-	Professional and non-professional	Yes
Bag	50 g	Polyethylene plastic (PET)	PP/PE	Professional and non-professional	Yes

[1] Type of packaging e.g. bottle, rolls, can, barrel, tank.
[2] Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.
For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height*Length*Width for rolls / number and weight of wipes.
[3] For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.
[4] Intended user, e.g. professional, non-professional

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa	Internal method CC/001/ccq	50% w/w of Saccharomyces cerevisae, yeast 30 % w/w of powdered egg	Yellow powder	Lodi M., 2021, Report No. 21022-02C, Renolab S.r.l.
3.1.1.	Physical state at 20 °C and 101.3 kPa	Internal method CC/001/ccq	50% w/w of Saccharomyces cerevisae, yeast 30 % w/w of powdered egg	Powder	Lodi M., 2021, Report No. 21022-02C, Renolab S.r.l.
3.1.2.	Colour at 20 °C and 101.3 kPa	Internal method CC/001/ccq	50% w/w of Saccharomyces cerevisae, yeast 30 % w/w of powdered egg	Yellow	Lodi M., 2021, Report No. 21022-02C, Renolab S.r.l.
3.1.3.	Odour at 20 °C and 101.3 kPa	Internal method CC/001/ccq	50% w/w of Saccharomyces cerevisae, yeast 30 % w/w of powdered egg	None	Lodi M., 2021, Report No. 21022-02C, Renolab S.r.l.
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75 (Determination of pH Values)	50% w/w of Saccharomyces cerevisae, yeast 30 % w/w of powdered egg	pH before storage: 7.96 pH after storage: 7.90	Lodi M., 2021, Report No. 21022-02C, Renolab S.r.l.
3.3.	Relative density / bulk density	CIPAC MT 186 (Bulk Density)	50% w/w of Saccharomyces cerevisae, yeast 30 % w/w of powdered egg	The pour density of FLY IN is 0.65 g/mL and the tap density is 0.72 g/mL	Lodi M., 2021, Report No. 21022-02C, Renolab S.r.l.
3.4.1.1.	Storage stability test – **accelerated storage**	CIPAC MT 46.3 (Storage Stability)	50% w/w of Saccharomyces cerevisae, yeast	The physical-chemical properties investigated before and after accelerated storage	Lodi M., 2021, Report No. 21022-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			30 % w/w of powdered egg	were comparable, and are in compliance with the requirement of the appropriate clauses. The type of packaging is suitable for the formulation. The method of analysis provided in this study aimed to detect and quantify the yeasts powdered, as CFU/g and spore/g, present in the Flay-In bait test item (Batch N° 210125) after accelerated storage. The test item was assessed as high quality formulation product with a spore density comparable to the values obtained in study 21022-01C. While following the accelerated storage a decrease of about 99.99% in the vitality of the yeasts (CFU / g) was found.	02C, Renolab S.r.l.
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**			Ongoing	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	The product must not be stored under conditions of ≤ 0°C then the low temperature storage does not need to be addressed.			
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	The product is stored in darkness, so no effect of light is expected.			

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Please refer to storage stability tests.			
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Please refer to storage stability tests.			
3.5.1.	Wettability *[indicate the concentration tested]*	Not applicable according Art. 25 of BPR Regulation			
3.5.2.	Suspensibility, spontaneity, and dispersion stability *[indicate the concentration tested]*	Not applicable according Art. 25 of BPR Regulation			
3.5.3.	Wet sieve analysis and dry sieve test *[indicate the concentration tested]*	Not applicable according Art. 25 of BPR Regulation			
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability *[indicate the concentration tested]*	Not applicable according Art. 25 of BPR Regulation			
3.5.5.	Disintegration time	Not applicable according Art. 25 of BPR Regulation			
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability *[the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed.]*	Not applicable according Art. 25 of BPR Regulation			
3.5.7.	Persistent foaming *[indicate the concentration tested]*	Not applicable			
3.5.8.	Flowability/pourability/dustability	Not applicable according Art. 25 of BPR Regulation			

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.9.	Burning rate — smoke generators	Not applicable			
3.5.10.	Burning completeness — smoke generators	Not applicable			
3.5.11.	Composition of smoke — smoke generators	Not applicable			
3.5.12.	Spraying pattern — aerosols / spray	Not applicable			
3.6.1.	Physical compatibility	The product is not applied in combination with other products, so further studies are not needed.			
3.6.2.	Chemical compatibility	The product is not applied in combination with other products, so further studies are not needed.			
3.7.	Degree of dissolution and dilution stability *(indicate the concentration tested)*	Not applicable according Art. 25 of BPR Regulation			
3.8.	Surface tension *[indicate the conditions of the test and the concentration tested]*	Not applicable according Art. 25 of BPR Regulation			
3.9.	Viscosity *[indicate the shear rate and the temperature tested]*	Not applicable according Art. 25 of BPR Regulation			

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
FLY IN is a soluble powder. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. - **Implications for labelling:** "let in diffusion 3 days inside the water before set it into the infested places"

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	The product does not contain any explosive components.		
4.2.	Flammable gases	Not applicable		
4.3.	Flammable aerosols	Not applicable		
4.4.	Oxidising gases	Not applicable		
4.5.	Gases under pressure	Not applicable		
4.6.	Flammable liquids	Not applicable		
4.7.	Flammable solids	The product does not contain any flammable components.		
4.8.	Self-reactive substances and mixtures	Not applicable		
4.9.	Pyrophoric liquids	Not applicable		
4.10.	Pyrophoric solids	Not applicable		
4.11.	Self-heating substances and mixtures	Not applicable		
4.12.	Substances and mixtures which in contact with water emit flammable gases	Not applicable		
4.13.	Oxidising liquids	Not applicable		
4.14.	Oxidising solids	The product does not contain any components with oxidizing properties.		
4.15.	Organic peroxides	Not applicable		
4.16.	Corrosive to metals	Not applicable		
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Not applicable		
4.17.2.	Relative self-ignition temperature for solids	Not applicable		
4.17.3.	Dust explosion hazard	Not applicable		

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards.

3.4 Methods for detection and identification

According to the information provided in Art. 20.1b of EU 528/2012, no data concerning methods for detection and identification are required for products meeting the conditions laid down in Art. 25 of the same regulation (simplified procedure). Noneless, some basic informacion is provided.

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Principle of the method*:* Direct Detection of Spore Density / Indirect detection of spore density
The test item Fly-In bait was characterized in order to determine the content of the active substance.
The test item is a homogeneously suspendable formulation, characterized by yeast and powder eggs. The characterization of the test item was performed through the following determinations:

- Direct detection of spore density: a spore suspension with known amount of test item was prepared and examined by microscopic techniques;
- Indirect detection of spore density: the method relies on cultivated techniques to establish the amount of viable propagates in the test item;

The results of the determination of the active ingredient content are summarized in the following table:

Batch	Spore density (Direct)	Spore density (Indirect)
	Spore/g	CFU/g
210125	3.20E+09	6.89E+08

Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Saccharomyces cerevisae, yeast and powdered egg	-	-	-	-	-	-	-	-	-	-	Lodi M. 2021, Report No. 21022-01C, Renolab S.r.l.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
The method of analysis provided in this study detect and quantified the yeasts powdered, as CFU/g and spore/g, present in the Flay-In bait test item (Batch N° 210125). The test item was assessed as high quality formulation product with a high percentage of viable spores and a high spore density. No analytical method has been validated for the active substance powdered egg as it is not technically feasible.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

Function: Attractant (PT19) The product FLY IN is an attractant to be used in traps against flies (*Musca domestica*, *Stomoxys calcitrans*)

Field of use: The product is intended to be used outdoors in different types of locations like houses, public institutions, shops, industries and animal housing.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

The product contains a mixture of ingredients that attract flies to a trap where they ultimately die. The insects attracted by the product composition (food grade attractants) enter the trap, then they get trapped and ultimately, they die because they cannot get out of the trap.

3.5.3 Efficacy data

Table 3.8 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
PT19 Use # 1: Fly in – Fly trap to fill with water	FLY IN	Flies: *Musca domestica* and *Stomoxys calcitrans*	**Test method:** Test environment: Outdoors or in open buildings **Test system:** The test is conducted outdoor or in open buildings highly infested by flies Musca domestica and Stomoxys calcitrans. 5 sites are monitored per species. In each site, a location where flies are numerous is chosen. In these locations, two traps were set closely, one with the attractant and one without the attractant (only water). The traps are filled with water according to the level recommended on the packaging. The attractant is let in diffusion 3 days inside the water before set it into the infested places. Rate: 1 trap per 100 m2 Application: The number of flies trapped is counted 5 days after placement in 5 of them, after 10 days in another 5, and after 15 days in another 5. Replicates: 5 Control: Trap with water Assessments: After 5, 10 and 15 days **Exposure time:** 15 days	The traps containing the product showed very good efficacy (more than 90% of trapping for both species). Validation criteria has not been validated.	Serrano, B. 2020. Report No. 2573/0620. TEC	6.7.1/Field trial of the efficacy of the trap "FLY IN" against flies.
PT19	FLY IN – 2-years old	Flies: *Musca domestica*	**Test method:** To check the efficacy of a 2-years old trap against flies in real conditions	In the conditions of the trial, with the samples	Serrano, B. 2022.	6.7.2/Field trial of the

Use # 1: Fly in – Fly trap to fill with water	sample – Batch 210125	and *Stomoxys calcitrans*	of use, using the same methodology than for the fresh sample. **Test system:** The test is conducted outdoor or in open buildings highly infested by flies *Musca domestica* and *Stomoxys calcitrans.* 5 sites are monitored per species. In each site, the best location where flies are numerous is chosen. The 5 sites are the 5 replicates, in each site 3 traps with the attractant and 3 traps without the attractant (only water) are set, each one to be collected at different dates. Then, in each site, 6 traps traps were set, 3 with the attractant and 3 without the attractant (only water). Rate: 1 trap per 100 m2 Application: The traps are filled with water according to the level recommended on the packaging. The attraction will start to cath lies about 3 days after it is placed in the infested places. The traps are hung at 1.8 m from the ground. There were 3 traps with the attractant per site and another 3 traps with only water (and not the attractant) per site. 5 sites per species were monitored, than 30 traps are monitored per species. The trial on the two species are separate and there were 5 sites monitored for houseflies and 5 sites monitored for stable flies = 10 sites in total. Replicates: 5 Control: Trap with water Assessments: After 5, 10 and 15 days	provided, strains and methodology used, the product: **FLY IN, fly trap containing its attractant product** **Aged 2 years** has proved a very good attractiveness towards house flies *Musca domestica* and stable flies *Stomoxys calcitrans.*	Report No. 2573b/0620. TEC	efficacy of the trap "FLY IN" against flies.

			Exposure time: 15 days			

3.5.4 Efficacy assessment

The number of flies trapped is counted 5 days after placement in 5 of them, after 10 days in another 5, and after 15 days in another 5.

Timeline :

Day0 : the traps are fileld ith water. The attractant is set in the water in half of them.

Day3 : all the traps are placed in the infested sites

Day3+5 : 5 traps with attractant and their correrssponding 5 traps without attractant are emptied and the number of insects trapped is recorded

Day3+10 : 5 other traps with attractant and their correrssponding 5 traps without attractant are emptied and the number of insects trapped is recorded

Day3+15 : the 5 last traps with attractant and their correrssponding 5 traps without attractant are emptied and the number of insects trapped is recorded.

The counts are done at the same hour of the day.

Formula for calculating the percentage of efficacy:

$$\frac{\text{Population trapped with attractant - Population trapped without attractant}}{\text{Population trapped with attractant}} \times 100$$

3.5.5 Conclusion on efficacy

In the conditions of the trial, with the sample provided, strains and methodology used, the product: "Fly in - fly trap" containing its attractant product has proved a very good attractiveness towards house flies *Musca domestica* and stable flies *Stomoxys calcitrans*.

The results will be extrapolated to the product "Fly In - Exclusive Formulation for traps" as the product formulation is the same.

3.5.6 Occurrence of resistance and resistance management

Given the mechanism of action of the product, the development of resistance would not be expected.

3.5.7 Known limitations

No undesirable or unintended side effects have been observed in any of the tests performed.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

The product is not intended to be used with other products.

3.6 Risk assessment for human health

According to the information provided in Art. 20.1b of EU 528/2012, no human health risk assessment is required for products meeting the conditions laid down in Art. 25 of the same regulation (simplified procedure).

The product does not contain any substance of concern (SoC) and its application does not require the use of protective personal equipment (PPE).

In this context, it must be noted that none of the substances included in this biocidal product would be considered a SoC in accordance with the guidance CA-Nov14-Doc.5.11, which defines the criteria for the identification of SoC. Additionally, no PPE is required for the use of these products because it is not classified according to Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures.

3.6.1 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).

3.7 Risk assessment for animal health

According to the information provided in Art. 20.1b of EU 528/2012, no animal health risk assessment is required for products meeting the conditions laid down in Art. 25 of the same regulation (simplified procedure).

3.8 Risk assessment for the environment

According to the information provided in Art. 20.1b of EU 528/2012, no environmental risk assessment is required for products meeting the conditions laid down in Art. 25 of the same regulation (simplified procedure).

3.9 Assessment of a combination of biocidal products

The product is not applied in combination with other products.

3.10 Comparative assessment

Not relevant.
FLY IN does not contains any active substances that is a candidate for substitution.

4 Appendices

4.1 Calculations for exposure assessment

Not applicable

4.2 New information on the active substances and substance(s) of concern

No new information on the active substances is available.

No substance of concern is present.

4.3 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/** **IUCLID Section No.**	**IUCLID Document name**	**Title.** **Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Lodi M.	2021	2.2.2 (PAR Section) 3.1, 3.2, 3.3, 3.4.1 (IUCLID section)	3.1.Appearance_Renolab 21022-02C 3.2.pH_Renolab 21022-02C 3.3.Bulk, tap density (solids)_Renolab 21022-02C 3.4.1. Accelerated Storage stability test_Renolab 21022-02C	Determination of the Physical-Chemical properties of the Product Fly-In bait Before and After Accelerated Storage for 2 weeks at 54±2 °C 21022-02C	Study report	Source: Renolab S.r.l. Study sponsor: S.R. LAST SHIELD LIMITED	Yes	Yes
Lodi M.	2021	2.2.4 (PAR Section) 5 (IUCLID section)	5.Method of detection and identification_Renolab 21022-01C	Determination of the Physical-Chemical properties of the Product Fly-In bait Before and After Accelerated Storage for 2 weeks at 54±2 °C 21022-02C	Study report	Source: Renolab S.r.l. Study sponsor: S.R. LAST SHIELD LIMITED	Yes	Yes

Serrano B.	2020	2.2.5 (PAR Section) 6.7 (IUCLID setion)	6.1.Field test against flies_TEC_1573/0620	Field trial of the efficacy of the trap "fly in" against flies. 2533/0620	Study report	Source: T.E.C. Laboratory Study sponsor: S.R. LAST SHIELD LIMITED	Yes	Yes
Serrano B.	2022	2.2.5 (PAR Section) 6.7 (IUCLID setion)	6.1.Field test against flies_TEC_2573b/0620	Field trial of the efficacy of the trap "fly in" against flies (2 years old sample) 2573b/0620	Study report	Source: T.E.C. Laboratory Study sponsor: S.R. LAST SHIELD LIMITED	Yes	Yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

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4.4.2 Guidance documents

- "Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 3.0 - April 2018 - ECHA".

4.4.3 Legal texts

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.