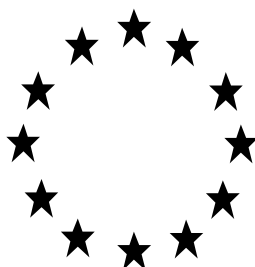


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FOR SIMPLIFIED
AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



FLYREX NEW

Product type 19

Powdered egg as included in the Annex I of Regulation
(EU) No 528/2012

Case Number in R4BP: BC-US066586-96

Evaluating Competent Authority: Italy

Date: July 2022

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1 CONCLUSION

FLYREX NEW is an attractant (PT19) containing the active substance powdered egg at 30.0% w/w and it is intended to be used as attractant bait against flies.

The product can be used outdoor by trained professional and professional users in stables, shelters and animal houses in general; by trained professional, professional and general public users in waste management sites and by professional and general public users in houses, storage rooms, warehouses, industries (including food processing industries) and other domestic or commercial premises.

Based on the assessment, the IT CA concludes that this product is sufficiently efficacious against target organisms and it can be safely used in outdoor environment according to the use instructions of the SPC.

Furthermore, taking into account that:

- The active substance powdered egg appears in Annex I to the BPR and ~~comply~~ complies with the specified restrictions;
- FLIREX NEW does not contain any substance of concern;
- FLIREX NEW does not contain any nanomaterials;
- the handling of FLIREX NEW and its intended use do not require personal protective equipment.

The conditions for granting an authorisation according to Article 25 of Regulation (EU) No 528/2012 are fulfilled.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	Country (if relevant)
FLYREX NEW	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	NEWPHARM S.r.l.
	Address	Via Tremarende 22 - 35010 - Santa Giustina in Colle (PD) Italy
Authorisation number	-	
Date of the authorisation	-	
Expiry date of the authorisation	-	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	NEWPHARM S.r.l.
Address of manufacturer	Via Tremarende 22 - 35010 - Santa Giustina in Colle (PD) Italy
Location of manufacturing sites	Via Tremarende 22 - 35010 - Santa Giustina in Colle (PD) Italy

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Powdered egg
Name of manufacturer	Parmovo Srl
Address of manufacturer	Frazione Sanguigna, 21- 43052 COLORNO (Parma) - Italy
Location of manufacturing sites	Frazione Sanguigna, 21- 43052 COLORNO (Parma) - Italy

2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No (not applicable, Annex I substance)

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Powdered egg
IUPAC or EC name	Powdered egg
EC number	na
CAS number	na
Index number in Annex VI of CLP	na
Minimum purity / content	Not relevant
Structural formula	Not relevant

2.1.2.2 Candidate(s) for substitution

Powdered egg does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. It is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Powdered egg	Powdered egg	Active substance	na	na	30

Please refer to the confidential annex for the full composition of the product. The biocidal product FLYREX NEW does not contain nanomaterials as required for simplified authorisation.

2.1.2.3 Information on technical equivalence

Not applicable.

The substance is included in Annex I of the BPR. No reference specifications are available.

2.1.2.4 Information on the substance(s) of concern

No substances of concern were identified in the product formulation (requirement for simplified authorisation).

For more information on the co-formulants, please refer to the confidential annex.

2.1.2.5 Type of formulation

Granules (GR)

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	None
Hazard statement	None
Labelling	
Signal words	None
Hazard statements	None
Precautionary statements	P102 Keep out of reach of children. P103 Read carefully and follow all instructions.
Note	/

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – ATTRACTANT BAIT FOR FLIES FOR STABLES AND OTHER ANIMAL HOUSING

Product Type	PT 19 – Repellents and attractants
Where relevant, an exact description of the authorised use	Granular bait for use in traps to attract flies in stables, shelters and animal houses in general
Target organism (including development stage)	<i>Musca domestica</i> - House fly – Adults <i>Lucilia sericata</i> - Sheep blow fly - Adult <i>Stomoxys calcitrans</i> - Stable flies - Adults
Field of use	Outdoor
Application method(s)	Bait applications in animal houses like stables or shelters
Application rate(s) and frequency	Bait application Pour the product into a trap, add water without mixing and place the trap outdoor of zootechnical premises. 50 grams every 10-15 meters 50 grams in 1,5 litre of water The product is efficient until 30 to 60 days depending on the temperature and the degree of infestation. If needed, it should be replaced at the end of this period.
Category(ies) of users	Trained professional / Professional
Pack sizes and packaging material	25-50-75-100-200-250-500 grams HDPE/PP jar with cap 750 grams PP bucket with cap 1-2-2,5-5-10 kgs PP bucket with cap 25 kgs HDPE drum with cap

2.1.4.2 Use-specific instructions for use

Always read the label before use. The granule baits will be dispersed in water without mixing inside suitable containers/traps with at least 1,5 L volume. The containers will be closed to avoid spillage and possibility to be opened by animals and children. The holes on the top of the containers will allow flies to enter and reach the attractant solution. Place the trap outside the stables away from pathways and reach of animals at height of 1,5 meter from the floor. Use one bait every 10-15 meters in relation with the degree of infestation. Do not place the bait point near walls. Place the bait point protected from wind. Check regularly the bait trap to avoid full evaporation of water and refill up to the original volume. Once the trap is full of dead insects, the trap can be removed or replaced if needed.

2.1.4.3 Use-specific risk mitigation measures

Product only contains food grade ingredients. No risk is expected for people and animals if product is used according to given instructions for use.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5 General directions for use

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5 General directions for use

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5 General directions for use

2.1.4.7 Use description

Table 2. Use # 2 – ATTRACTANT BAIT FOR FLIES FOR WASTE MANAGEMENT AREAS

Product Type	PT 19 – Repellents and attractants
Where relevant, an exact description of the authorised use	Granular bait for use in traps to attract flies in waste management areas
Target organism (including development stage)	<i>Musca domestica</i> - House fly - Adults
Field of use	Outdoor
Application method(s)	Bait applications for use in traps in waste management sites
Application rate(s) and frequency	Bait application Pour the product into a trap, add water without mixing and place the trap outdoor waste management sites. 50 grams every 10-15 meters 50 grams in 1,5 litre of water The product is efficient until 30 to 60 days depending on the temperature and the degree of infestation. If needed, it should be replaced at the end of this period.
Category(ies) of users	Trained professional / Professional / General Public (non professional)
Pack sizes and packaging material	25-50-75-100-200-250-500 grams HDPE/PP jar with cap 750 grams PP bucket with cap 1-2-2,5-5-10 kgs PP bucket with cap 25 kgs HDPE drum with cap

2.1.4.8 Use-specific instructions for use

Always read the label before use. The granule baits will be dispersed in water without mixing inside suitable containers/traps with at least 1,5 L volume. The containers will be closed to avoid spillage and possibility to be opened by animals and children. The holes on the top of the containers will allow flies to enter and reach the attractant solution. Place the trap at height of 1,5 meter from the floor. Use one bait point every 10-15 meters in relation with the degree of infestation. Do not place the bait point near walls. Place the bait point protected from wind. Check regularly the bait trap to avoid full evaporation of water and refill up to the original volume. Once the trap is full of dead insects, the trap can be removed or replaced if needed.

2.1.4.9 Use-specific risk mitigation measures

Product only contains food grade ingredients. No risk is expected for people and animals if product is used according to given instructions for use.

2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5 General directions for use

2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5 General directions for use

2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5 General directions for use

2.1.4.13 Use description

Table 3. Use # 3 – ATTRACTANT BAIT FOR FLIES FOR DOMESTIC, COMMERCIAL AND INDUSTRIAL PREMISES

Product Type	PT 19 – Repellents and attractants
Where relevant, an exact description of the authorised use	Granular bait for use in traps to attract flies in houses, storage rooms, warehouses, industries (including food processing industries) and other domestic or commercial premises
Target organism (including development stage)	<i>Musca domestica</i> - House fly – Adults <i>Lucilia sericata</i> - Sheep blow fly - Adults
Field of use	Outdoor
Application method(s)	Bait applications for use in traps in houses, storage rooms, warehouses and other domestic or commercial premises
Application rate(s) and frequency	Bait application Pour the product into a trap, add water without mixing and place the trap outdoor houses, storage rooms, warehouses and other domestic or commercial premises. 50 grams every 10-15 meters 50 grams in 1,5 litre of water The product is efficient until 30 to 60 days depending on the temperature and the degree of infestation. If needed, it should be replaced at the end of this period.
Category(ies) of users	Professional / General public (non-professional)
Pack sizes and packaging material	25-50-75-100-200-250-500 grams HDPE/PP jar with cap

2.1.4.14 Use-specific instructions for use

Always read the label before use. The granule baits will be dispersed in water without mixing inside suitable containers/traps with at least 1,5 L volume. The containers will be closed to avoid spillage and possibility to be opened by animals and children. The holes on the top of the containers will allow flies to enter and reach the attractant solution. Place the trap at height of 1,5 meter from the floor. Use one bait every 10-15 meters in relation with the degree of infestation. Do not place the bait point near walls. Place the bait point protected from wind. Check regularly the bait trap to avoid full evaporation of water and refill up to the original volume. Once the trap is full of dead insects, the trap can be removed or replaced if needed.

2.1.4.15 Use-specific risk mitigation measures

Product only contains food grade ingredients. No risk is expected for people and animals if product is used according to given instructions for use.

2.1.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5 General directions for use

2.1.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5 General directions for use

2.1.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5 General directions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

See use specific directions for use. Inform the authorization holder if the treatment is ineffective.

2.1.5.2 Risk mitigation measures

Product only contains food grade ingredients. No risk is expected for people and animals if product is used according to given instructions for use.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Not expected. Product only contains food-grade ingredients.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Unused product can be disposed in the organic waste. Do not release the empty container in the environment. Empty containers can be disposed in plastic collection points for recycling.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Keep the product in original container, away from food and feedingstuff. Avoid at extreme temperatures and exposure of sun light.
Shelf-life: 2 years.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging Weight FLYREX NEW	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Jar TVA0130PE	130 ml 25-50 g	HDPE – PP	Cap bottle - LDPE	Trained professional / Professional / General public (non-professional)	Yes

Jar TPE0250PE	270 ml 75-100 g	HDPE - PP	Cap bottle - LDPE	Trained professional / Professional / General public (non- professional)	Yes
Jar TPS0560PE/2	500 ml 200-250 g	HDPE - PP	Cap bottle - LDPE	Trained professional / Professional / General public (non- professional)	Yes
Jar TPE1050PE	1050 ml 500 g	HDPE - PP	Cap bottle - LDPE	Trained professional / Professional / General public (non- professional)	Yes
Jar QTV1150PE	1000 ml 500 g	HDPE - PP	Cap bottle - LDPE	Trained professional / Professional / General public (non- professional)	Yes
Small bucket MU20M2	2200 ml 750-1000 g	PP	Cap bottle - PP	Trained professional / Professional	Yes
Bucket MU4700M3	4800 ml 2 Kg	PP	Cap bottle - PP	Trained professional / Professional	Yes
Bucket MU5700_3	5800 ml 2.5 Kg	PP	Cap bottle - PP	Trained professional / Professional	Yes
Bucket MU11700	11500 ml 5 Kg	PP	Cap bottle - PP	Trained professional / Professional	Yes
Bucket MU18600	19300 ml 10 Kg	PP	Cap bottle - PP	Trained professional / Professional	Yes
Drum PL1261	50 l 25 Kg	HDPE	Cap bottle - HDPE	Trained professional / Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Efficacy test and stability test were performed on the product. All of these data are submitted within the current application.

No other studies have been performed in accordance with Art.25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of Regulation 528/2012.

2.1.8.2 Access to documentation

A Letter of Access is not applicable for products eligible for simplified authorisation under Article 25 of the BPR, for which the active substances are on Annex I of the BPR (category 4).

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

2.2.1.1 Use description

Table 4. Use # 1 – ATTRACTANT BAIT FOR FLIES FOR STABLES AND OTHER ANIMAL HOUSING

Product Type	PT 19 – Repellents and attractants
Where relevant, an exact description of the authorised use	Granular bait for use in traps to attract flies in stables, shelters and animal houses in general
Target organism (including development stage)	<i>Musca domestica</i> - House fly - Adults <i>Lucilia sericata</i> - Sheep blow fly - Adult <i>Stomoxys calcitrans</i> - Stable flies - Adults
Field of use	Outdoor
Application method(s)	Bait applications for use in traps in animal houses, like stables or shelters
Application rate(s) and frequency	Bait application Pour the product into a trap, add water without mixing and place the trap outdoor of zootechnical premises. 50 grams every 10-15 meters 50 grams in 1,5 litre of water One application every 30-60 days, in relation with the temperature and degree of infestation.
Category(ies) of users	Trained professional / Professional
Pack sizes and packaging material	25-50-75-100-200-250-500 grams HDPE/PP jar with cap 750 grams PP bucket with cap 1-2-2,5-5-10 kgs PP bucket with cap 25 kgs HDPE drum with cap

2.2.1.2 Use description

Table 5. Use # 2 – ATTRACTANT BAIT FOR WASTE MANAGEMENT AREAS

Product Type	PT 19 – Repellents and attractants
Where relevant, an exact description of the authorised use	Granular bait for use in traps to attract flies in waste management areas
Target organism (including development stage)	<i>Musca domestica</i> - House fly - Adults
Field of use	Outdoor
Application method(s)	Bait applications for use in traps in waste management sites
Application rate(s) and frequency	Bait application Pour the product into a trap, add water without mixing and place the trap outdoor waste management sites. 50 grams every 10-15 meters 50 grams in 1,5 litre of water One application every 30-60 days, in relation with the temperature and degree of infestation.

Category(ies) of users	Trained professional / Professional
Pack sizes and packaging material	25-50-75-100-200-250-500 grams HDPE/PP jar with cap 750 grams PP bucket with cap 1-2-2,5-5-10 kgs PP bucket with cap 25 kgs HDPE drum with cap

2.2.1.3 Use description

Table 6. Use # 3 – ATTRACTANT BAIT FOR DOMESTIC AND COMMERCIAL PREMISES

Product Type	PT 19 – Repellents and attractants
Where relevant, an exact description of the authorised use	Granular bait for use in traps to attract flies in houses, storage rooms, warehouses and other domestic or commercial premises
Target organism (including development stage)	<i>Musca domestica</i> - House fly – Adults <i>Lucilia sericata</i> - Sheep blow fly - Adult
Field of use	Outdoor
Application method(s)	Bait applications for use in traps in houses, storage rooms, warehouses and other domestic or commercial premises
Application rate(s) and frequency	Bait application Pour the product into a trap, add water without mixing and place the trap outdoor houses, storage rooms, warehouses and other domestic or commercial premises. 50 grams every 10-15 meters 50 grams in 1,5 litre of water One application every 30-60 days, in relation with the temperature and degree of infestation.
Category(ies) of users	Professional / General public (non-professional)
Pack sizes and packaging material	25-50-75-100-200-250-500 grams HDPE/PP jar with cap

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual assessment	Test item: FLYREX NEW Active ingredient: (Powdered egg) Active ingredient content: 30.0 % w/w Batch number: 01/2021	Solid	
Colour at 20 °C and 101.3 kPa	Visual assessment	Test item: FLYREX NEW Active ingredient: (Powdered egg) Active ingredient content: 30.0 % w/w Batch number: 01/2021	Light brownish	
Odour at 20 °C and 101.3 kPa	Olfactory assessment	Test item: FLYREX NEW Active ingredient: (Powdered egg) Active ingredient content: 30.0 % w/w Batch number: 01/2021	Light rotten smell	FLYREX NEW: ACCELERATED STORAGE STABILITY TEST OF FLYREX NEW, A READY TO USE ATTRACTIVE LURE FOR FLIES. GLP Study No. 17/2021. March 03, 2021. Test Facility: BUCCIARELLI LABORATORI - Ascoli Piceno (AP) Italy IUCLID: 3.1
Acidity / alkalinity	The method is based on CIPAC method MT 75.3	Test item: FLYREX NEW Active ingredient: (Powdered egg) Active ingredient content: 30.0 % w/w	Sample number 3208/2021 (T0) pH= 6.42 3209/2021 (T1) pH= 6.44	FLYREX NEW: ACCELERATED STORAGE STABILITY TEST OF FLYREX NEW, A READY TO USE ATTRACTIVE

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Batch number: 01/2021	3210/2021 (T2) pH= 6.45	LURE FOR FLIES. GLP Study No. 17/2021. March 03, 2021. Test Facility: BUCCIARELLI LABORATORI - Ascoli Piceno (AP) Italy IUCLID: 3.2
Relative density / bulk density	-	-	-	Determination of physical, chemical and technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Storage stability test – accelerated storage	Accordance with CIPAC MT 46.3, using an HPLC equipped with a MS/MS selective detector and triphenyl phosphate (TPP) as internal standard and organoleptic method. pH: The method is based on	Test item: FLYREX NEW Active ingredient: (Powdered egg) Active ingredient content: 30.0 % w/w Batch number: 01/2021	After 2 weeks of storage at 54°C, the active ingredient content and the physico-chemical properties of the test item were comparable to the relevant values obtained in the initial characterisation . The determination of the cholesterol content was	FLYREX NEW: ACCELERATED STORAGE STABILITY TEST OF FLYREX NEW, A READY TO USE ATTRACTIVE LURE FOR FLIES. GLP Study No. 17/2021. March 03, 2021. Test Facility: BUCCIARELLI LABORATORI - Ascoli Piceno (AP) Italy IUCLID 3.4.1

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	CIPAC MT 75.3.		<p>used as an indicator of content of powdered eggs in FLYREX NEW samples.</p> <p>Cholesterol concentration 3208/2021: non aged. 3209/2021: one week aged 3210/2021: two week aged Results: 3208/2021 (T0): Sample Weight (g): 2.1352 Cholesterol (mg/l): 15.08 Cholesterol (mg/Kg): 706.2</p> <p>3209/2021 (T1): Sample Weight (g): 2.0116 Cholesterol (mg/l): 13.98 Cholesterol (mg/Kg): 694.9</p> <p>3209/2021 (T2): Sample Weight (g): 1.9253 Cholesterol (mg/l): 13.27 Cholesterol (mg/Kg): 6689.2</p> <p>Appearance of container No changes in the appearance or integrity of the HDPE plastic bottle</p>	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			<p>were observed over the storage interval. Sample without visible breaks and/or color changes.</p> <p>Wheight loss Sample number: 3209/2021 (T1) Initial Weight (g): 250.610 Final Weight (g): 250.520 Weight loss (g): -0.090 Weight loss (%): 0.036</p> <p>Sample number: 3210/2021 (T2) Initial Weight (g): 247.279 Final Weight (g): 247.175 Weight loss (g): -0.104 Weight loss (%): -0.042</p> <p>Apparence No changes in the appearance of the sample were observed over the storage interval. The sample appears as a light brown powder, no chromatic changes are detected.</p> <p>Odour</p>	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			No changes in the odour (light rotten smell) of the sample were observed over the storage interval. pH Sample number 3208/2021 (T0): 6.42 3209/2021 (T1): 6.44 3210/2021 (T2): 6.45	
Storage stability test – long term storage at ambient temperature	NA	NA	NA	NA
Storage stability test – low temperature stability test for liquids	NA	NA	NA	NA
Effects on content of the active substance and technical characteristics of the biocidal product - light	NA	NA	NA	NA
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	NA	NA	NA	NA
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	NA	NA	NA	NA
Wettability	-	-	-	Determination of physical, chemical and

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
				technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Suspensibility, spontaneity and dispersion stability	-	-	-	Determination of physical, chemical and technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Wet sieve analysis and dry sieve test	-	-	-	Determination of physical, chemical and technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Emulsifiability, re-emulsifiability and emulsion stability	-	-	-	Not applicable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Disintegration time	-	-	-	Determination of physical, chemical and technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Particle size distribution, content of dust/fines, attrition, friability	-	-	-	Determination of physical, chemical and technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Persistent foaming	-	-	-	Not applicable
Flowability/Pourability/Dustability	-	-	-	Determination of physical, chemical and technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
				20(1)(b) of EU 528/2012.
Burning rate — smoke generators	-	-	-	Not applicable
Burning completeness — smoke generators	-	-	-	Not applicable
Composition of smoke — smoke generators	-	-	-	Not applicable
Spraying pattern — aerosols	-	-	-	Not applicable
Physical compatibility	-	-	-	Not applicable. FLYREX NEW is used alone.
Chemical compatibility	-	-	-	Not applicable. FLYREX NEW is used alone.
Degree of dissolution and dilution stability	-	-	-	Determination of physical, chemical and technical properties is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Surface tension	-	-	-	Not applicable
Viscosity	-	-	-	Not applicable

Conclusion on the physical, chemical and technical properties of the product

FLYREX NEW is a brownish granular bait with light rotten odour.
 Conclusion on the accelerated storage stability test of FLYREX NEW.
 No significant change in the concentration of Cholesterol (used as an indicator of content of powdered eggs) in the FLYREX NEW formulation aged 7 and 14 days at 54°C +/- 2 ° C compared to the non-aged sample. No changes in the appearance or integrity of the plastic bottle were observed over the storage interval. No change changes in the physical properties were observed. The sample can be considered stable.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Explosives	-	-	The product does not contain substances with associated chemical groups with explosive properties and is therefore not considered explosive. The biocidal product fulfills the conditions for simplified authorization, i.e. has no hazard classification.	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Flammable gases	-	-	Not applicable.	-
Flammable aerosols	-	-	Not applicable	-
Oxidising gases	-	-	Not applicable	-
Gases under pressure	-	-	Not applicable	-
Flammable liquids	-	-	Not applicable	-
Flammable solids	-	-	Not applicable/non-flammable. The product do not contain any flammable components. The biocidal product fulfills the conditions for simplified authorization, i.e. has no hazard classification.	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Self-reactive substances and mixtures	-	-	Not applicable/not-classified (the biocidal product fulfills the	Accordance with Art. 25 of Regulation 528/2012 (simplified

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			conditions for simplified authorization, i.e. has no hazard classification)	procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Pyrophoric liquids	-	-	Not applicable.	-
Pyrophoric solids	-	-	Not applicable/not-classified (the biocidal product fulfills the conditions for simplified authorization, i.e. has no hazard classification)	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Self-heating substances and mixtures	-	-	Not applicable/not-classified (the biocidal product fulfills the conditions for simplified authorization, i.e. has no hazard classification)	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Substances and mixtures which in contact with water emit flammable gases	-	-	Not applicable/not-classified (the biocidal product fulfills the conditions for simplified authorization, i.e. has no hazard classification)	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Oxidising liquids	-	-	Not applicable.	-
Oxidising solids	-	-	Not applicable / not oxidizing. The product does not contain components with oxidizing properties. The biocidal product fulfills the	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			conditions for simplified authorization, i.e. it does not have a hazard classification.	
Organic peroxides	-	-	Not applicable, none of the products within the biocide is based on organic peroxides. The biocidal product fulfills the conditions for simplified authorization, i.e. has no hazard classification.	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Corrosive to metals	-	-	Not applicable	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Auto-ignition temperatures of products (liquids and gases)	-	-	Not applicable.	-
Relative self-ignition temperature for solids	-	-	Not applicable/not-classified (the biocidal product fulfills the conditions for simplified authorization, i.e. has no hazard classification)	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012.
Dust explosion hazard	-	-	Not applicable/not-classified (the biocidal product fulfills the conditions for	Accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			simplified authorization, i.e. has no hazard classification)	detailed in Art. 20(1)(b) of EU 528/2012.

Conclusion on the physical hazards and respective characteristics of the product

This is no data requirement for an application in accordance with Art. 25 of Regulation 528/2012 (simplified procedure) as detailed in Art. 20(1)(b) of EU 528/2012. In line with the simplified authorization criteria, the FLYREX NEW biocidal product is not classified for physical hazards.

2.2.4 Methods for detection and identification

The analytical method developed for the determination of the active ingredient in the accelerated storage study is based on the determination of cholesterol. The rationale behind the choice of cholesterol as a target for the determination of the active ingredient is based on the fact that cholesterol is a representative component of the active substance contained in the FLYREX NEW product.

Operating procedure

The active ingredient, egg powder, is determined utilizing cholesterol and indicator and quantified by an HPLC system equipped with a triple quadrupole detector.

Calibration solutions

Triphenyl Phosphate Solution 100 mg/l

In a 100 ml volumetric flask class A dissolve 0.0100 g of triphenyl phosphate, add 50 ml of methanol and put the flask in the ultrasonic bath for ten minutes dissolve completely. Leave the solution at room temperature for 15 minutes and finally dilute to volume with methanol.

Cholesterol solution: 1.12 g/l

In a 100 ml volumetric flask class A have been dissolved 0.1131 g of cholesterol, add 50 ml of methanol and put the flask in the ultrasonic bath for ten minutes dissolve completely. Leave the solution at room temperature for 15 minutes and finally dilute to volume with methanol.

STD cholesterol 11.2 mg/l

in a 10 ml vial mix 9800 µl of methanol with 100 µl of cholesterol solution, add 100 µl of internal standard TPP and agitate by vortex. The solution is ready to be injected into the HPLC system.

STD cholesterol 22.4 mg/l

in a 10 ml vial mix 9700 µl methanol with 200 µl of cholesterol solution, add 100 µl of internal standard TPP and agitate by vortex. The solution is ready to be injected into the HPLC system.

STD cholesterol 33.6 mg/l

in a 10 ml vial mix 9600 µl of methanol with 300 µl of cholesterol solution, add 100 µl of internal standard TPP and agitate by vortex. The solution is ready to be injected into the HPLC system.

Sample preparation

In a 100 ml class A volumetric flask are weighed 2.0000 g of aged/non aged FLYREX NEW formulation containing the active ingredients to be tested, add 50 ml of methanol and put the flask in the ultrasonic bath for fifteen minutes.

Leave the solution at room temperature for 15 minutes, add 1 ml of internal standard TPP and finally dilute to volume with methanol.

The solution is ready to be injected into the HPLC system.

PUMP GRADIENT RAMP	% A Formic acid 0.1 % in water and ammonium formate 5mM	% B Formic acid - 0.1 % in methanol and ammonium formate 5mM
0.00 min	70	30
2.00 min	40	60
4.00 min	0	100
7.00 min	0	100
7.01 min	70	30
10.00 min	70	30

PRECISION

The maximum RSD between six replicates in the validation program must be less than 5%

RSD max Cholesterol : 2.50 %

LINEARITY

The observed linear correlation coefficient R^2 must be ≥ 0.9900 and R^2 Cholesterol = 0.9961.

Response factor RSD $\leq 20\%$

Response factor RSD max Cholesterol: 10.2 %

ACCURACY

The mean recovery of six replicates in the validation program must be between 90% - 110%
mean recovery Cholesterol: 98.3%

SPECIFICITY

The specificity of the method is guaranteed by:

Relative retention time: retention time of the Cholesterol peak compared to that of the standard (tolerance: +/- 2.5%)

Mass spectrum of the Cholesterol peak compared to that of the standard, the laboratory evaluates the intensity ratio of the 2 qualifier ion compared to the quantifier ions.

quantifier	qualifier	Intensity (%)	Tolerance (%)
147.20	161.15	98.2	± 30
147.20	105.10	63.8	± 30

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Not required in the frame of a simplified national authorisation.

Active substance is listed in Annex I of regulation (EU) No 528/2012 under Category 4.

Conclusion on the methods for detection and identification of the product

The analytical methods of analysis for the determination of powdered eggs in the product is acceptable.

The monitoring methods for water, sediment and soil are not required as active substance is listed in Annex I of Regulation (EU) 528/2012.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Evaluation of the efficacy as attractant of FLYREX NEW, formulated as granule baits made of egg powder and other organic ingredients, which attract flies from considerable distance, creating aggregation points. *Musca domestica* and *Lucilia sericata* will be the main target pests, but all fly species (e.g. *Sarcophaga carnaria*, *Calliphora vomitoria*, ecc.) present into the test environment will be assessed. FLYREX NEW will be used in outdoor applications in zootechnical (e.g. stables, animal shelters in general) and civil environments (e.g. food industries, camping sites, landfills, farms, holiday resorts, etc.). FLYREX NEW (fresh batch) will be compared with an artificially aged formulation (14 days at 54°C), to evaluate the attractant efficacy of the baits at the end of claimed storage period.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

FLYREX NEW is proposed for *Musca domestica* and *Lucilia sericata*, these will be the main target pests, but all fly species (e.g. *Sarcophaga carnaria*, *Calliphora vomitoria*, ecc.) present into the test environment will be assessed.

2.2.5.3 Effects on target organisms, including unacceptable suffering

FLYREX NEW is an attractant, formulated as granule baits made of egg powder and other organic ingredients.

2.2.5.4 Mode of action, including time delay

FLYREX NEW is an attractant, formulated as granule baits made of egg powder and other organic ingredients, which attract flies from considerable distance, creating aggregation points. Once dispersed in water, the bait undergoes a fermentation process that attracts flies. This process is typical of egg powder and is assisted by the other proteins present in the formulation. The mechanism of action of FLYREX NEW is indirect mechanical in that it consists of a trap containing an attractant against the target organisms.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)

Function	PT19 Attractant
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Field of use envisaged	Outdoor (around buildings)		
Test substance	Test item: FLYREX NEW Active ingredient: (Powdered egg) Active ingredient content: 30.0 % w/w		
Test organism(s)	<i>Musca domestica</i> <i>Lucilia sericata</i> Other fly species		
Test method	Guidelines: ECHA Guidance on the Biocidal Products Regulation. Volume II Efficacy Assessment and Evaluation (Parts B+C). Version 3. April 2018.		
Test system / concentrations applied / exposure time	<p>3 replicates will be set up in different types of environment, but covering more representative zootechnical and civil environments. The granule baits will be dispersed in water without mixing inside proper tamper-proof containers/traps with at least 1,5 L volume. The containers will be closed to avoid spillage and possibility to be opened by animals and childrens. The hole on the top of the containers will allow flies to enter and reach the attractant solution. Containers will be placed outside, around buildings, at 150 m height from the ground, 10-15 m away from each other and away from the walls. The number of traps will depend on the size and specific features of each trial site.</p> <p>Treatment 1 Water only. Treatment 2 FLYREX NEW (FRESH BAIT) - Egg powder 30% - 50 g/1,5 L water Treatment 3 FLYREX NEW (AGED BAIT) - Egg powder 30% - 50 g/1,5 L water Both water only (treatment 1) and the test item (treatments 2 and 3) were placed into the same type of containers. The containers were kept closed to avoid spillage and possibility to be opened by animals and children. The hole on the top of the containers allowed flies to enter and reach the attractant solution. In order to perform the traps monitoring, 2 visits were carried out during the first 3 weeks after baits placement. One visit per week was then performed until the baits lost their effectiveness or until 60 days after placement. At each visit the number of flies present inside each trap was counted. Individuals belonging to different species were counted and reported separately.</p>		
Test results: effects	Results of the monitoring of insects captures during the trial period		
	Sicily - Breeding stable Number of captures/trap		
	Untreated check Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (aged bait) Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0
	Untreated check Date: 19 April 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 19 April 2021 Musca domestica 51.2 Lucilia sericata 7.2 Stomoxys calcitrans 0.7	FLYREX NEW (aged bait) Date: 19 April 2021 Musca domestica 10.5 Lucilia sericata 4.0 Stomoxys calcitrans 0

Untreated check Date: 23 April 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 23 April 2021 Musca domestica 141.7 Lucilia sericata 14.3 Stomoxys calcitrans 2.5	FLYREX NEW (aged bait) Date: 23 April 2021 Musca domestica 55.5 Lucilia sericata 7.0 Stomoxys calcitrans 2.0
Untreated check Date: 26 April 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 26 April 2021 Musca domestica 137.7 Lucilia sericata 17.8 Stomoxys calcitrans 3.5	FLYREX NEW (aged bait) Date: 26 April 2021 Musca domestica 89 Lucilia sericata 10 Stomoxys calcitrans 1.5
Untreated check Date: 30 April 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 30 April 2021 Musca domestica 574.3 Lucilia sericata 146.8 Stomoxys calcitrans 14	FLYREX NEW (aged bait) Date: 30 April 2021 Musca domestica 455.0 Lucilia sericata 109.5 Stomoxys calcitrans 10
Untreated check Date: 3 May 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 3 May 2021 Musca domestica 570.2 Lucilia sericata 145.5 Stomoxys calcitrans 12.7	FLYREX NEW (aged bait) Date: 3 May 2021 Musca domestica 481.5 Lucilia sericata 79.5 Stomoxys calcitrans 10.5
Untreated check Date: 10 May 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 10 May 2021 Musca domestica 1256.2 Lucilia sericata 329 Stomoxys calcitrans 28.3	FLYREX NEW (aged bait) Date: 10 May 2021 Musca domestica 993 Lucilia sericata 278 Stomoxys calcitrans 18
Untreated check Date: 17 May 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 17 May 2021 Musca domestica 1272.5 Lucilia sericata 608.3 Stomoxys calcitrans 44.7	FLYREX NEW (aged bait) Date: 17 May 2021 Musca domestica 1109.0 Lucilia sericata 504.0 Stomoxys calcitrans 43.5
Untreated check Date: 24 May 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 24 May 2021 Musca domestica 1318.3 Lucilia sericata 588.3 Stomoxys calcitrans 40.7	FLYREX NEW (aged bait) Date: 24 May 2021 Musca domestica 1107.5 Lucilia sericata 475.0 Stomoxys calcitrans 39.5
Untreated check Date: 31 May 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 31 May 2021 Musca domestica 1225.0 Lucilia sericata 526.7 Stomoxys calcitrans 29.3	FLYREX NEW (aged bait) Date: 31 May 2021 Musca domestica 895.0 Lucilia sericata 495.0 Stomoxys calcitrans 32.5
Untreated check Date: 7 June 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 7 June 2021 Musca domestica 1043.3 Lucilia sericata 403.3 Stomoxys calcitrans 33.5	FLYREX NEW (aged bait) Date: 7 June 2021 Musca domestica 900.0 Lucilia sericata 367.5 Stomoxys calcitrans 32.5
Untreated check Date: 14 June 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 14 June 2021 Musca domestica 770.0 Lucilia sericata 268.3 Stomoxys calcitrans 21.3	FLYREX NEW (aged bait) Date: 14 June 2021 Musca domestica 615.0 Lucilia sericata 255.0 Stomoxys calcitrans 26.5
Untreated check Date: 21 June 2021 Musca domestica 0 Lucilia sericata 0 Stomoxys calcitrans 0	FLYREX NEW (fresh bait) Date: 21 June 2021 Musca domestica 601.7 Lucilia sericata 190.0 Stomoxys calcitrans 13.7	FLYREX NEW (aged bait) Date: 21 June 2021 Musca domestica 480.0 Lucilia sericata 185.0 Stomoxys calcitrans 13.0
Campania - Buffalo breeding stable Number of captures/trap		
Untreated check Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (aged bait) Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0
Untreated check Date: 19 April 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 19 April 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (aged bait) Date: 19 April 2021 Musca domestica 0 Lucilia sericata 0
Untreated check Date: 23 April 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 23 April 2021 Musca domestica 6 Lucilia sericata 1.4	FLYREX NEW (aged bait) Date: 23 April 2021 Musca domestica 3.3 Lucilia sericata 2.8
Untreated check Date: 26 April 2021	FLYREX NEW (fresh bait) Date: 26 April 2021	FLYREX NEW (aged bait) Date: 26 April 2021

Musca domestica 0 Lucilia sericata 0	Musca domestica 21.2 Lucilia sericata 8.7	Musca domestica 13.8 Lucilia sericata 7.3
Untreated check Date: 30 April 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 30 April 2021 Musca domestica 23.5 Lucilia sericata 6.9	FLYREX NEW (aged bait) Date: 30 April 2021 Musca domestica 18.3 Lucilia sericata 4.8
Untreated check Date: 3 May 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 3 May 2021 Musca domestica 12.6 Lucilia sericata 26	FLYREX NEW (aged bait) Date: 3 May 2021 Musca domestica 91.8 Lucilia sericata 15
Untreated check Date: 10 May 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 10 May 2021 Musca domestica 271 Lucilia sericata 60.4	FLYREX NEW (aged bait) Date: 10 May 2021 Musca domestica 227.5 Lucilia sericata 45.8
Untreated check Date: 17 May 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 17 May 2021 Musca domestica 256.4 Lucilia sericata 47.6	FLYREX NEW (aged bait) Date: 17 May 2021 Musca domestica 197.5 Lucilia sericata 47.5
Untreated check Date: 24 May 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 24 May 2021 Musca domestica 289.7 Lucilia sericata 32.7	FLYREX NEW (aged bait) Date: 24 May 2021 Musca domestica 235.8 Lucilia sericata 23.7
Untreated check Date: 31 May 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 31 May 2021 Musca domestica 301.4 Lucilia sericata 31.6	FLYREX NEW (aged bait) Date: 31 May 2021 Musca domestica 250.0 Lucilia sericata 25.3
Untreated check Date: 7 June 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 7 June 2021 Musca domestica 189.2 Lucilia sericata 14.7	FLYREX NEW (aged bait) Date: 7 June 2021 Musca domestica 148.0 Lucilia sericata 12.5
Untreated check Date: 14 June 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 14 June 2021 Musca domestica 136.5 Lucilia sericata 12.2	FLYREX NEW (aged bait) Date: 14 June 2021 Musca domestica 130.0 Lucilia sericata 11.5
Untreated check Date: 21 June 2021 Musca domestica 0 Lucilia sericata 0	FLYREX NEW (fresh bait) Date: 21 June 2021 Musca domestica 49.8 Lucilia sericata 6.3	FLYREX NEW (aged bait) Date: 21 June 2021 Musca domestica 6.3 Lucilia sericata 5.3
Campania - Cheese factory Number of captures/trap		
Untreated check Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (aged bait) Date: 16 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0
Untreated check Date: 19 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 19 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (aged bait) Date: 19 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0
Untreated check Date: 23 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 23 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (aged bait) Date: 23 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0
Untreated check Date: 26 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 26 April 2021 Musca domestica 7.2 Lucilia sericata 0.8 Calliphora vicina 0.6	FLYREX NEW (aged bait) Date: 26 April 2021 Musca domestica 4 Lucilia sericata 0.5 Calliphora vicina 0.5
Untreated check Date: 30 April 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 30 April 2021 Musca domestica 11.6 Lucilia sericata 2.6 Calliphora vicina 0.6	FLYREX NEW (aged bait) Date: 30 April 2021 Musca domestica 8.5 Lucilia sericata 2.5 Calliphora vicina 0.5
Untreated check Date: 3 May 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 3 May 2021 Musca domestica 21.6 Lucilia sericata 7.4 Calliphora vicina 1.8	FLYREX NEW (aged bait) Date: 3 May 2021 Musca domestica 18.5 Lucilia sericata 9.0 Calliphora vicina 2.0

	Untreated check Date: 10 May 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 10 May 2021 Musca domestica 131 Lucilia sericata 19.4 Calliphora vicina 1.6	FLYREX NEW (aged bait) Date: 10 May 2021 Musca domestica 120 Lucilia sericata 18 Calliphora vicina 1.5
	Untreated check Date: 17 May 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 17 May 2021 Musca domestica 141 Lucilia sericata 19.4 Calliphora vicina 3.4	FLYREX NEW (aged bait) Date: 17 May 2021 Musca domestica 116.5 Lucilia sericata 19.5 Calliphora vicina 3.5
	Untreated check Date: 24 May 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 24 May 2021 Musca domestica 127.0 Lucilia sericata 20.6 Calliphora vicina 3.2	FLYREX NEW (aged bait) Date: 24 May 2021 Musca domestica 115.0 Lucilia sericata 18.5 Calliphora vicina 2.5
	Untreated check Date: 31 May 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 31 May 2021 Musca domestica 99.8 Lucilia sericata 13.8 Calliphora vicina 3.6	FLYREX NEW (aged bait) Date: 31 May 2021 Musca domestica 90.0 Lucilia sericata 12.5 Calliphora vicina 3.5
	Untreated check Date: 7 June 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 7 June 2021 Musca domestica 95.4 Lucilia sericata 12.8 Calliphora vicina 3.8	FLYREX NEW (aged bait) Date: 7 June 2021 Musca domestica 82.5 Lucilia sericata 11.5 Calliphora vicina 3.5
	Untreated check Date: 14 June 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 14 June 2021 Musca domestica 79.4 Lucilia sericata 15.2 Calliphora vicina 3.4	FLYREX NEW (aged bait) Date: 14 June 2021 Musca domestica 63.5 Lucilia sericata 12.0 Calliphora vicina 2.5
	Untreated check Date: 7 June 2021 Musca domestica 0 Lucilia sericata 0 Calliphora vicina 0	FLYREX NEW (fresh bait) Date: 7 June 2021 Musca domestica 52.0 Lucilia sericata 10.4 Calliphora vicina 2.2	FLYREX NEW (aged bait) Date: 7 June 2021 Musca domestica 43.5 Lucilia sericata 8.0 Calliphora vicina 1.5
Reference	Final Report Efficacy evaluation of FLYREX NEW, used as attractant baits against Musca domestica, Lucilia sericata and other fly species in zootechnical and civil environments – Italy 2021 - Final report Trial code: 2024.BCD.SAG21 - Testing Facility: SAGEA Centro di Saggio s.r.l. - Via San Sudario, 15 - 12050 Castagnito d’Alba (CN) Italy. 13 Jul 2021		

Conclusion on the efficacy of the product

The efficacy as attractant of FLYREX NEW, formulated as granule baits made of egg powder and other organic ingredients, was assessed. FLYREX NEW (Fresh bait) was compared with FLYREX NEW (Aged bait), an artificially aged formulation (14 days at 54°C), to evaluate the attractant efficacy of the baits at the end of claimed storage period. Three replicates of the test were set up in different regions, to cover more representative sites: buffalo stable in Campania region and hen stable in Sicily region (zootechnical environments) and a cheese factory in Campania region (civil environment).

The granule baits were dispersed in water without mixing inside proper tamper-proof containers (traps) with at least 1,5 L water volume. The traps were placed outside, around buildings, at about 150 cm height from the ground, 10-15 m away from each other, away from the walls and far enough from anything which might interfere with its attractant power (e.g. manure-heaps, sewage, fermented organic materials).

Traps without test item granules, but only containing water, were placed at each site as untreated controls.

The traps were placed at each site on April 12th.

The traps were controlled twice per week during the first 3 weeks after baits placement. One visit per week was then performed until 70 days after placement. At each visit the number of flies present inside each trap was counted. Individuals belonging to different species were counted and reported separately. *Musca domestica* and *Lucilia sericata* were the main target pests counted during the traps monitoring, but also individuals of *Stomoxys calcitrans* and *Calliphora vomitoria* were detected. All the traps containing Flyrex New (both Fresh bait and Aged bait) showed a noticeable effectiveness in attracting and capturing flies present in the three trial sites. Moreover, the results obtained at 70 days after traps placement indicates a remarkable persistence of the traps attractiveness covering a period longer than 2 months.

2.2.5.6 Occurrence of resistance and resistance management

Not expected to be relevant for FLYREX NEW product.

2.2.5.7 Known limitations

There are no known limitations to the product.

2.2.5.8 Evaluation of the label claims

The claim is supported by data. Considering the assessments performed until May 17th it was possible to state that all the traps containing Flyrex New (both Fresh bait and Aged bait) showed a noticeable effectiveness in attracting and capturing flies present in the three trial sites.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

FLYREX NEW is not intended to be authorised for use with other biocidal products.

2.2.6 Risk assessment

2.2.7 For human health

According to Article 25 a simplified authorisation procedure may be applied where the product does not contain any substance of concern (SoC), and the handling of the biocidal product and its intended use do not require personal protective equipment (PPE).

The product FLYREX NEW does not contain any classified ingredient and, hence, it is not classified.

Moreover, there are no substances of concern present, therefore it is considered that a detailed exposure assessment is not relevant under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.7.1 Assessment of effects on Human Health

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant
Justification for the value/conclusion	Overall, the biocide does not contain active substances or co-formulants classified as dangerous under the CLP Regulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	According to the information requirement of BPR, testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture based on the rules of CLP Regulation (EC) n. 1272/2008.
Justification	FLYREX NEW contains Powdered eggs as active ingredient and other organic ingredients and no substances of concern. The biocidal product does not meet the classification criteria.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritant
Justification for the value/conclusion	Overall, the biocide does not contain active substances or co-formulants classified as dangerous under the CLP Regulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	According to the information requirement of BPR, testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture based on the rules of CLP Regulation (EC) n. 1272/2008.

Justification	FLYREX NEW contains Powdered eggs as active ingredient and other organic ingredients and no substances of concern. The biocidal product does not meet the classification criteria.
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Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Overall, the biocide does not contain active substances or co-formulants classified as dangerous under the CLP Regulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	-
Justification	FLYREX NEW contains Powdered eggs as active ingredient and other organic ingredients and no substances of concern. The biocidal product does not meet the classification criteria.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing
Justification for the value/conclusion	Overall, the biocide does not contain active substances or co-formulants classified as dangerous under the CLP Regulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	According to the information requirement of BPR, testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture based on the rules of CLP Regulation (EC) n. 1272/2008.
Justification	FLYREX NEW contains Powdered eggs as active ingredient and other organic ingredients and no substances of concern. The biocidal product does not meet the classification criteria.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing
Justification for the value/conclusion	Overall, the biocide does not contain active substances or co-formulants classified as dangerous under the CLP Regulation.

Classification of the product according to CLP and DSD	Not classified
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Data waiving	
Information requirement	There are currently no standard tests and no OECD TG available for respiratory tract sensitisation and there is no testing requirement for this endpoint under the BPR.
Justification	FLYREX NEW contains Powdered eggs as active ingredient and other organic ingredients and no substances of concern. The biocidal product does not meet the classification criteria.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not classified
Justification for the selected value	Acute oral toxicity data are not available for the product. All ingredients of the product are not classified under the CLP Regulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture.
Justification	FLYREX NEW contains Powdered eggs as active ingredient and other organic ingredients and no substances of concern. The biocidal product does not meet the classification criteria.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not classified
Justification for the selected value	Acute inhalation toxicity data are not available for the product. All ingredients of the product are not classified under the CLP Regulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
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Information requirement	Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture.
Justification	FLYREX NEW contains Powdered eggs as active ingredient and other organic ingredients and no substances of concern. The biocidal product does not meet the classification criteria.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not classified
Justification for the selected value	Acute dermal toxicity data are not available for the product. No ingredients of the product are classified under the CLP Regulation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture.
Justification	FLYREX NEW contains Powdered eggs as active ingredient and other organic ingredients and no substances of concern. The biocidal product does not meet the classification criteria.

Information on dermal absorption

Not relevant

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

There are no substance(s) of concern identified in the product FLYREX NEW according to the criteria laid out in Annex A of the guidance on the BPR, Vol III, Parts B+C.

Available toxicological data relating to a mixture

Mixtures containing substances of concern are not present in the biocidal product.

Other

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Endocrine-disrupting properties for human health: screening for co-formulants

Screening of endocrine-disruptors properties of co-formulants has been performed according to CG document "Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants".

Overall, based on available information it is concluded that the product does not contain co-formulants with endocrine disruptor properties for human.

Please, refer to the Annex of Confidential Data for further details.

2.2.7.2 Exposure assessment

Information on human health exposure of the biocidal product FLYREX NEW is not relevant for a simplified authorisation.

Taking into account that there are no substances of concern present, that the biocidal product FLYREX NEW is not classified, and due to the data requirements for Simplified procedure according to Regulation (EU) 528/2012 exposure assessment is not relevant.

2.2.7.3 Risk characterisation for human health

The formulation FLYREX NEW has been considered in relation to the simplified authorisation procedure (under Reg. (EU) 528/2012, article 25). An assessment of potential SOC's (Substances of Concern) has been made. The co-formulants are either not classified as hazardous to human health under Reg. (EC) 1272/2008. On this basis, the approval of FLYREX NEW should be authorized from the point of view of human health according to the simplified authorisation procedure (Reg. (EU) 528/2012, art. 25).

2.2.8 Risk assessment for animal health

There are no substances of concern present FLYREX NEW and the product is not classified, therefore a risk assessment for animal health is not relevant under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.9 Risk assessment for the environment

The product FLYREX NEW is not classified and does not contain any classified ingredient or substance of concern. Therefore a risk assessment for the environment is not required under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.9.1 Effects assessment on the environment

The product FLYREX NEW is not classified and does not contain any classified ingredient or substance of concern.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Data on the ecotoxicity of the product are not available. Data are available for each component of the product and, following the application of the classification rules of Annex I of the CLP Regulation, the product is not classified, as required for simplified authorisation.

Further Ecotoxicological studies

Not relevant under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No data available.

Supervised trials to assess risks to non-target organisms under field conditions

No data available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No data available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No data available.

Foreseeable routes of entry into the environment on the basis of the use envisaged

No data available.

Further studies on fate and behaviour in the environment (ADS)

No data available.

Leaching behaviour (ADS)

No data available.

Testing for distribution and dissipation in soil (ADS)

No data available.

Testing for distribution and dissipation in water and sediment (ADS)

No data available.

Testing for distribution and dissipation in air (ADS)

No data available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

No data available.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

No data available.

Endocrine-disrupting properties for environment: screening for co-formulants

Screening of endocrine-disruptors properties of co-formulants has been performed according to CG document "Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants".

Overall, based on available information it is concluded that the product does not contain co-formulants with endocrine disruptor properties for environment.

Please, refer to the Annex of Confidential Data for further details.

2.2.9.2 Exposure assessment

The product FLYREX NEW is not classified and does not contain any classified ingredient or substance of concern. An exposure assessment is not required under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.9.3 Risk characterisation

The product FLYREX NEW is not classified and does not contain any classified ingredient or substance of concern. An exposure assessment is not required under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.10 Measures to protect man, animals and the environment

The product FLYREX NEW is not classified and does not contain any classified ingredient or substance of concern. Specific measures to protect man, animals and the environment are not required for the product, comply with the instructions for use. See section 2.1.4.

2.2.11 Assessment of a combination of biocidal products

Not relevant. FLYREX NEW is not intended to be authorised for the use with other biocidal products.

3 ANNEXES

3.1 List of studies for the biocidal product

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Date of first submission
De Angelis, R.	2021	ACCELERATED STORAGE STABILITY TEST OF FLYREX NEW, A READY-TO-USE ATTRACTIVE LURE FOR FLIES	Yes	Newpharm S.r.l.	May 2021
Rovetto, I.	2021	Efficacy evaluation of FLYREX NEW, used as attractant baits against <i>Musca domestica</i> , <i>Lucilia sericata</i> and other fly species in zootechnical and civil environments – Italy 2021	Yes	Newpharm S.r.l.	July 2021

3.2 Output tables from exposure assessment tools

Not applicable.

3.3 New information on the active substance

New information on the active substance is not available.

3.4 Residue behaviour

No residues of FLYREX NEW in food or feed occur.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Please, see section 2.2.5.5

3.6 Confidential annex

Please cf. to separate document.