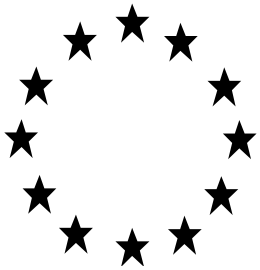
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATIONS



[Fly Attract]

Product type(s) [19]

[*Saccharomyces cerevisiae,* Powdered egg and D-Fructose as as included in the Union list of approved active substances : Annex I]

Case Number in R4BP: [BC-DM066680-35]

Evaluating Competent Authority: [BE CA]

Date: [01/02/2022]

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1 CONCLUSION

The product Fly Attract is a wettable powder intendend to be used in an appropriate trap placed outdoor to attract flies. The attractant contains 10% of *Saccharomyces cerevisiae,* 20% of powdered egg and 40% of D-fructose as the active ingredients. It is intended to be used by professionals and non-professionals.

For the biocidal product Fly Attract it has been established that sufficient data have been provided to verify the outcome and conclusions and that all conditions are met to permit authorization of the biocidal product in accordance with article 25 of Regulation (EU) No 528/2012:

(a) the active substance contained in the biocidal product appears in Annex I, and no restrictions apply to the substance;
(b) the biocidal product does not contain any substance of concern;
(c) the biocidal product does not contain any nanomaterials;
(d) the biocidal product is sufficiently effective; and
(e) the handling of the biocidal product and its intended use do not require personal protective equipment.

Composition and classification

The biocidal product Fly Attract contains 10% of *Saccharomyces cerevisiae,* 20% of powdered egg and 40% of D-fructose as active substances, who are listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

The biocidal product is not classified according to Regulation (EU) No. 1272/2008, and contains no substances of concern. Its handling does not require any personal protective equipment.

Physico-chemistry

Determination of physical, chemical and technical properties is not a data requirement for an application in accordance with Art.25 of EU 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012. The properties of the Fly Attract have therefore not been assessed. However, some restrictions should be added to the label ("Do not store at temperatures above 30°C" ; "Store away from light"). No physicochemical stability study has been carried out. Indeed, the shelf-life of the product will be supported solely by efficacy results on aged samples (see section 2.2.5).

Considering the composition of the product and the fact that the active substance is included in Annex I of the BPR, it can be concluded that the product presents no physical hazards.

[redacted]

The analytical methods for the determination of the active substances D-fructose, yeast and egg powder [redacted] in the product are acceptable.
The analytical methods have been validated for the linearity [redacted] precision, accuracy and specificity.
Analytical methods for monitoring, soil, air, water, animal and human body fluids and tissues, for monitoring of active substances and residues in food and feeding stuff are not required for simplified authorisations.

Efficacy

The product Fly Attract is an attractant powder for flies. The powder should be diluted at a dose of 40 g into 600 mL of water, which should be applied in a suitable fly trap. To attract flies, the filled trap should be used outdoors.
Fly Attract in combination with a trap is effective to attract flies during at least 11 days after the application of the product.
Furthermore, the 2 years old Fly Attract product has shown good efficacy up to 11 days, therefore the product is considered stable up to 2 years of storage.

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[1]	**Country (if relevant)**
Fly attract	
Trade names	
Vliegenlokstof	Belgium
Attractif Mouches	Belgium/France/Luxembourg
Fliegen Lockstoff	Germany/Luxembourg
Attrattiva per Mosche	Italy
Atrayente para Mosca	Spain
BIOSTOP légy attraktáns	Hungary
BIOSTOP atraktant na mouchy	Czech Republic
BIOSTOP atraktant muchy	Slovakia
BIOSTOP atractantă pentru muşte	Romania

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Bio services International NV
	Address	Jagershoek 13 8570 Vichte Belgium
Authorisation number	EU-0027005-0000	
Date of the authorisation	01/02/2022	
Expiry date of the authorisation	04/02/2032	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Bio services International NV
Address of manufacturer	Jagershoek 13 8570 Vichte Belgium
Location of manufacturing sites	Jagershoek 13 8570 Vichte Belgium

1 Please fill in here the identifying product name from R4BP.

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

Active substance	*Saccharomyces cerevisiae*
Name of manufacturer	ALGIST BRUGGEMAN NV
Address of manufacturer	Langerbruggekaai 37 9000 Ghent Belgium
Location of manufacturing sites	Langerbruggekaai 37 9000 Ghent Belgium

Active substance	Powdered egg
Name of manufacturer	Schaffelaarbos B.V.
Address of manufacturer	Industrieweg 20 3771 MD Barneveld The Netherlands
Location of manufacturing sites	Industrieweg 20 3771 MD Barneveld The Netherlands

Active substance	D-Fructose
Name of manufacturer	Tate & Lyle Slovakia s.r.o.
Address of manufacturer	Boleraz 114 919 08 boleraz Slovakia
Location of manufacturing sites	Boleraz 114 919 08 boleraz Slovakia

Active substance	D-Fructose
Name of manufacturer	OMNIA NİŞASTA SAN. TİC. A.Ş.
Address of manufacturer	OMNIA NİŞASTA SAN. TİC. A.Ş. Hacı Sabancı OSB Yunus Emre Cad. No: 8 01410 Sarıçam/ADANA TURKEY
Location of manufacturing sites	OMNIA NİŞASTA SAN. TİC. A.Ş. Hacı Sabancı OSB Yunus Emre Cad. No: 8 01410 Sarıçam/ADANA TURKEY

2.1.2 Product composition and formulation

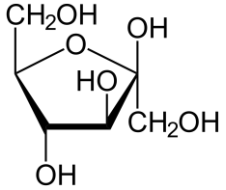
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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	*Saccharomyces cerevisiae*
IUPAC or EC name	-
EC number	-
CAS number	68876-77-7
Index number in Annex VI of CLP	-
Minimum purity / content	100%
	10^9 CFU/g
Structural formula	Not relevant

Main constituent(s)	
ISO name	D-Fructose
IUPAC or EC name	-
EC number	200-333-3
CAS number	57-48-7
Index number in Annex VI of CLP	-
Minimum purity / content	99.5%
Structural formula	

Main constituent(s)	
ISO name	Powdered egg
IUPAC or EC name	-
EC number	-
CAS number	-
Index number in Annex VI of CLP	-
Minimum purity / content	100%
Structural formula	Not relevant

2.1.2.2 Candidate(s) for substitution

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

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Saccharomyces cerevisiae	-	Active substance	68876-77-7	-	10.00
Powdered egg	-	Active substance	-	-	20.00
D-Fructose	-	Active substance	57-48-7	200-333-3	40.00 (TECH) 39.8 (PURE)

2.1.2.4 Information on technical equivalence

Not applicable.
The substances are included in annex I of the BPR. No reference specifications are available.

2.1.2.5 Information on the substance(s) of concern

No substances of concern were identified in the product formulation.
No alerts for endocrine disruptor were identified for the co-formulants. For more information on the co-formulants, please refer to the confidential annex.

2.1.2.6 Type of formulation

WP – Wettable Powder

2.1.3 Hazard and precautionary statements[3]

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	-
Hazard statements	-

2 Please delete as appropriate.

3 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Precautionary statements	
Note	-

2.1.4 Authorised use(s)

2.1.4.1 Use description[4]

Table 1. Use # 1 – Fly attractant – Professional / Non professional – Outdoor

Product Type	PT19 : Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	The product is used in an appropriate trap placed outdoor to attract flies.
Target organism (including development stage)	*Musca domestica* – House fly – Adults
Field of use	Outdoor
Application method(s)	Bait application To be used with a suitable trap
Application rate(s) and frequency	Add to the trap: 10g product per 150 ml water (amount of water depending on the trap size, for example, for 1 L trap : 40 g product diluted in 600 ml water) Effective up to 11 days
Category(ies) of users	Professional Non professional
Pack sizes and packaging material	For professionals and non professionals: - Water soluble bags (Primary packaging) : 10-20-30-40-50-60-70-80-90-100g in PVA or PVOH - Bags (secondary packaging: filled with water soluble bags): 40-2000g in PP, PE, AluFoil (consisting of OPP-MET-adhesive-PE-tie-(PA)-tie-PE), or (O)PP/PET 50/50 bag - Container (primary packaging: filled with water soluble bags) : 1L in PET - Bottle (primary packaging :filled with bulk product) : 1L in HDPE For professionals only: - Bucket (filled with bulk product) : 5-10L in PP

[4] Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

2.1.4.2 Use-specific instructions for use[5]

After filling the fly trap with water and FLY Attract (attractant) at a dosage of 10 g Fly Attract in 150 ml tap water, about 1/3rd of the space within the trap must remain free in order to have enough air-space available for the entry of flies.

For example: a fly trap of 1 liter can be filled with 40g in 600 ml (=4 x10 g=40 g in 4x 150 ml= 600 ml tap water). Depending on the number of flies present (resulting in high catches and less air space available in the trap(s)), the use of multiple traps may be considered.

2.1.4.3 Use-specific risk mitigation measures

-

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

-

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

-

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

-

[5] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.5 General directions for use

2.1.5.1 Instructions for use[6]

- *For non professionals :* Comply with the instructions for use.
- 'The product needs to be diluted in an appropriate trap and the trap needs to be placed outdoor
- For maximum efficacy, the trap needs to be suspended or fixed at a height around 2 meter of the ground.
- Product should be used with traps specifically designed to catch flies.

2.1.5.2 Risk mitigation measures

-

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

- *For non professionals :* If medical advice is needed, have product container or label at hand

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Dispose of content/container according to national regulation

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

- *For non professionals :* Keep out of reach of children and non-target animals/pets
- Store away from light
- Do not store at temperatures above 30°C
- Store at ambient temparure
- Shelf life: 2 years

2.1.6 Other information

-

2.1.7 Packaging of the biocidal product

[6] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

Type of packaging	Size/volume of the packaging	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)
Water soluble bags (*Primary packaging)*	10-20-30-40-50-60-70-80-90-100g	PVA (50-80µ)	Sealed bags	Non-professionals & Professionals	Yes
		PVOH			Yes
Bags (*secondary packagings filled with water soluble bags*)	40-2000g	PP			Yes
	40-2000g	PE			Yes
	40-2000g	Alu Foil (consisting of OPP-MET-adhesive-PE-tie-(PA)-tie-PE)			Yes
	40-2000g	(O)PP/PET 50/50 bag	PP head		Yes
Container (primary *packaging filled with water soluble bags)*	1L	PET	PP closure		Yes
Bottle (*primary packaging filled with bulk product)*	1L	HPDE	HPDE closure		Yes
Bucket (*primary packaging filled with bulk product)*	5 – 10 L	PP	PP	Professionals	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the Annex of this document to find the reference list.

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).
The applicant is the owner of all submitted data.

2.2 Assessment of the biocidal product (family)

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

Table 2. Use # 1 – Fly attractant – Professional / Non professional – Outdoor

Product Type	PT19 : Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	The product is used in an appropriate trap placed outdoor to attract Flies.
Target organism (including development stage)	*Musca domestica* – Adults
Field of use	Outdoor
Application method(s)	Product needs to be diluted with water. Please make sure that after filling the fly trap with water and FLY Attract (attractant) at a dosage of 10 g Fly Attract in 150 ml tap water – about 1/3rd of the space within the trap must remain free in order to have enough air-space available for the entry of flies. For example: a fly trap of 1 liter can be filled with 40g in 600 ml (=4 x10 g=40 g in 4x 150 ml= 600 ml tap water). Depending on the number of flies present (resulting in high catches and less air space available in the trap(s)), the use of multiple traps may be considered. The diluted product is placed in an appropriate trap and the trap is placed outdoor.
Application rate(s) and frequency	Add to the trap: 10g product per 150 ml water (amount of water depending on the trap size, for example, for 1 L trap : 40 g product diluted in 600 ml water) Effective up to 3 months
Category(ies) of users	Professional Non professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Determination of physical, chemical and technical properties is not a data requirement for an application in accordance with Art.25 of EU 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012. The properties of the product have therefore not been assessed.
No physicochemical stability study has been carried out. Indeed, the shelf-life of the product will be supported solely by efficacy results on aged samples.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	/	Fly Attract	Solid	MSDS
Colour at 20 °C and 101.3 kPa	/	Fly Attract	Yellow	MSDS
Odour at 20 °C and 101.3 kPa	/	Fly Attract	Caracteristic	MSDS
Acidity / alkalinity	Waived - Not required in the context of simplified authorisations.			
Relative density / bulk density	Waived - Not required in the context of simplified authorisations.			
Storage stability test – **accelerated storage**	Waived - No study performed. The shelf-life of the product will be set based on efficacy data on aged product (see section 2.2.5). **BE comment :** According to the Guidance on the BPR Vol I Parts A+B+C (May 2018), the following restriction "Do not store at temperatures above 30°C" should be added to the label if no accelerated storage test is performed.			
Storage stability test – **long term storage at ambient temperature**	Waived - No study performed. The shelf-life of the product will be set based on efficacy data on aged product (see section 2.2.5). Note: The determination of microbial contaminants in aged product has not been performed.			
Storage stability test – **low temperature stability test for liquids**	Waived - Not relevant considering the formulation type.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waived - No study performed. The sentence "Store away from light" will be on the label.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waived - No study performed. Humidity is not relevant considering that the packaging is water-resistant (plastic).			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Waived - No study performed. Both the product and the packaging material are inert.			
Wettability	Waived - Not required in the context of simplified authorisations.			
Suspensibility, spontaneity and dispersion stability	Waived - Not required in the context of simplified authorisations.			
Wet sieve analysis and dry sieve test	Waived - Not required in the context of simplified authorisations.			
Emulsifiability, re-	Waived - Not required considering the formulation type.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
emulsifiability and emulsion stability				
Disintegration time	Waived - Not required considering the formulation type.			
Particle size distribution, content of dust/fines, attrition, friability	Waived - Not required in the context of simplified authorisations.			
Persistent foaming	Waived - Not required considering the formulation type.			
Flowability/Pourability/Dustability	Waived - Not required in the context of simplified authorisations.			
Burning rate — smoke generators	Waived - Not required considering the formulation type.			
Burning completeness — smoke generators	Waived - Not required considering the formulation type.			
Composition of smoke — smoke generators	Waived - Not required considering the formulation type.			
Spraying pattern — aerosols	Waived - Not required considering the formulation type.			
Physical compatibility	Waived - Not required considering the formulation is not used in combination with other product(s).			
Chemical compatibility	Waived - Not required considering the formulation is not used in combination with other product(s).			
Degree of dissolution and dilution stability	Waived - Not required considering the formulation type.			
Surface tension	Waived - Not required considering the formulation type.			
Viscosity	Waived - Not required considering the formulation type.			

Conclusion on the physical, chemical and technical properties of the product
Determination of physical, chemical and technical properties is not a data requirement for an application in accordance with Art.25 of EU 528/2012 (simplified procedure) as detailed in Art.20(1)(b) of EU 528/2012. The properties of the Fly Attract have therefore not been assessed. However, some restrictions should be added to the label ("Do not store at temperatures above 30°C" ; "Store at ambient temperature" ; "Store away from light") No physicochemical stability study has been carried out. Indeed, the shelf-life of the product will be supported solely by efficacy results on aged samples (see section 2.2.5).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR –			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	category 4, and as such do not give rise to concern for explosiveness, this property is considered not applicable.			
Flammable gases	Waived - Not relevant because the product is a solid.			
Flammable aerosols	Waived - Not relevant because the product is a solid.			
Oxidising gases	Waived - Not relevant because the product is a solid.			
Gases under pressure	Waived - Not relevant because the product is a solid.			
Flammable liquids	Waived - Not relevant because the product is a solid.			
Flammable solids	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for flammability, this property is considered not applicable.			
Self-reactive substances and mixtures	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for self-reactivity, this property is considered not applicable.			
Pyrophoric liquids	Waived - Not relevant because the product is a solid.			
Pyrophoric solids	Waived - According to the additional classification considerations in CLP Annex I, 2.10.4, the classification procedure for pyrophoric solids need not be applied when experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance or mixture is known to be stable at room temperature for prolonged periods of time (days)). Since the product is known to be stable in contact with air, no classification is required and there is no need for testing.			
Self-heating substances and mixtures	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for self-heating, this property is considered not applicable.			
Substances and mixtures which in contact with water emit flammable gases	Waived - The product is known to be stable in contact with water and does not contain metals or metalloids. The product is therefore not classified and no testing is required.			
Oxidising liquids	Waived - Not relevant because the product is a solid.			
Oxidising solids	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for oxidising properties, this property is considered not applicable.			
Organic peroxides	Waived - Not relevant because the product does not fall under the definition of organic peroxides.			
Corrosive to metals	Waived - Not relevant because the product is a solid.			
Auto-ignition temperatures of products (liquids and gases)	Waived - Not relevant because the product is a solid.			
Relative self-ignition temperature for solids	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for self-ignition, this property is considered not applicable.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Dust explosion hazard	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for dust explosion, this property is considered not applicable.			

Conclusion on the physical hazards and respective characteristics of the product
Considering the composition of the product and the fact that the active substance is included in Annex I of the BPR, it can be concluded that the product presents no physical hazards.

2.2.4 Methods for detection and identification

[redacted]

	Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Precision**	**Reference**
					Range	Mean	RSD			
D-fructose	[redacted]	3 measurements (100% of D-Fructose)	Y= 0.002938x – 16.95367 R^2>0.999 Range : 484.43 mg/L to 20035.01 mg/L	[redacted]	95.50 – 97.00	96.33	0.79	-	38.90% of D-Fructose (5 measurements) RSDr: 1.69 Hr: 0.891	[redacted]
[redacted]										
[redacted]	[redacted]	3 measurements (100% of	[redacted]	[redacted]	99.28 – 99.90	99.48	0.36	-	9.28% of yeast (5	[redacted]

	[redacted]	yeast)		[redacted]					measurements) RSDr: 0.74 Hr: 0.390	[redacted]
[redacted]										
[redacted]	[redacted]	3 measurements [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]										

Analytical methods for monitoring, soil, air, water, animal and human body fluids and tisues, for monitoring of active substances and residues in food and feeding stuff are not required for simplified authorisations.

Conclusion on the methods for detection and identificationof the product

[redacted]

The analytical methods for the determination of the active substances D-fructose, yeast and egg powder [redacted] in the product are acceptable.
The analytical methods have been validated for the linearity [redacted] precision, accuracy and specificity.

Analytical methods for monitoring, soil, air, water, animal and human body fluids and tissues, for monitoring of active substances and residues in food and feeding stuff are not required for simplified authorisations.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product Fly Attract is a wettable powder with 10% saccharomyces cerevisae, 20% powdered egg and 40% D-fructose as active substance, to be used in outdoor areas to attract flies. Used in combination with a trap, it allows to catch these insects, reducing the inconvenience that they cause. It can be used by both professional and non-professional users.

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

Flies can be a nuisance and a hygiene pest due to the insect scavenging for foodstuffs and being a nuisance to humans. They normally frequent areas where animals or garbage is stored where they can pick up disease causing bacteria and parasites which they can then transfer.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product Fly Attract is used in combination with a trap. The insects are attracted and lured into the trap, which they cannot escape. Eventually, the flies get tired and will drown in the trap and die.

2.2.5.4 Mode of action, including time delay

It is expected that the attractant effect of the product Fly Attract is based on olfactory attraction. The product is effective when diluted with water into a trap.

2.2.5.5 Efficacy data

<table>
<tr><th colspan="7">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function/ Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>PT19 – Attractant for flies / Outdoor</td>
<td>Fly Attract

(10% saccharomyces cerevisae, 20% powdered egg, 40% D-fructose)

Fresh and after 2 years storage</td>
<td>Flies

Field population

(Musca domestica)</td>
<td>(Semi-) Field trial

Kinrooi, Belgium</td>
<td><u>Test system and exposure time :</u>
The test was performed in a simulated outdoor conditions (large volume, open access leaving the opportunity for the flies to stay or leave) in order to avoid the sudden death of individuals as the experiment occurred during winter.

12 replicates were set (10 in a 227m² space and 2 in a 10m² room). Each replicate was composed of one control trap (tap water), one reference product trap, one product Fly Attract trap and one 2 years old product Fly Attract trap.

For each replicate, 100 Musca domestica pupae were set in the cleanroom, therefore a total of ±1200 flies were present during the experiment. Nevertheless, the flies could quit the experiment at any time through an exit and flies that did not come from the setted pupae could also enter through the same way.

A first assessment was performed 12 days after application in the cleanroom (two traps) to demonstrate quick action of the attractant. A second assessment was performed on the other ten traps after 3 months.</td>
<td>1st assessment – 12 days after treatment (N=2) and 2nd assessment – 3 months after treatment (N=10). The total number of captured flies for each treatment is indicated in the table below :
<table>
<tr><td colspan="4"># captured house flies</td></tr>
<tr><td>Treatment</td><td>12 days</td><td>3 months</td><td>total</td></tr>
<tr><td>Control (tap water)</td><td>65</td><td>63</td><td>128</td></tr>
<tr><td>Fly Attract</td><td>332</td><td>380</td><td>722</td></tr>
<tr><td>Fly Attract (2 years)</td><td>217</td><td>1304</td><td>1521</td></tr>
</table>
After 12 days of treatment, 65 house flies were captured by the control trap whereas 332 were captured by the Fly Attract trap and 217 by the 2 years old Fly Attract trap.

After 3 months of treatment, 63 house flies were captured by the control trap whereas 380 were captured by the Fly Attract trap and 1304 by the 2 years old Fly Attract trap.

<u>Efficacy :</u> The efficacy compared to the control treatment is calculated :
<table>
<tr><th>Treatment</th><th>12 days</th><th>3 months</th><th>total</th></tr>
<tr><td>Fly Attract</td><td>80.4 %</td><td>83.4 %</td><td>82.2 %</td></tr>
<tr><td>Fly Attract (2 years)</td><td>70 %</td><td>95.2 %</td><td>91.6 %</td></tr>
</table>
Conclusion: Compared to water, the Fly Attract catches more flies.</td>
<td>Efficacy of attractants on an existing population of the house fly Musca domestica (Diptera: Muscidae) and other diptera species. (MUSCDO20-01A)</td>
</tr>
</table>

				The percentage of efficacy is calculated by comparing the number of insects trapped in the untreated and in the treated traps: % of efficacy = [(population trapped with attractant - population trapped without attractant) / population trapped with attractant] x 100. <u>Concentrations applied :</u> 40g of product Fly Attract diluted in 600mL of water in the trap.	2 years stored product shows less "quick effect" (70 % after 12 days), but demonstrates good efficacy up to 3 months (91.6 %). Fresh product demonstrates a stable efficacy rate of >80%, up to 3 months. However, only one observation per trap was made during the test. Therefore, an efficacy time of 11 days has been authorized.	

Conclusion on the efficacy of the product
Currently, no guidelines are available for efficacy testing of fly attractants. The applicant submitted a (semi-) field trial, where pupae are released into a large room with access to outdoor area, to simulate an outdoor area. As flies were free to leave the indoor area, the results of the semi-field trial can be extrapolated to an outdoor area. The pupae were released to ensure sufficient flies are present for testing. The available efficacy study demonstrates that the product Fly Attract, when used at 40g product diluted in 600 ml water inside a suitable trap, is effective to attract flies during a period of at least 3 months with a level of efficacy ranging from 70 up to 95%, with an average efficacy of 80%. Testing of Fly Attract product after 2 years has shown a potential delay in 'quick effect', but after 3 months of capturing flies, the aged product has shown good efficacy. It can be considered that the product is still efficacious after 2 years of storage. However, only one observation per trap was made during the test. Therefore, an efficacy time of 11 days has been authorized.

2.2.5.6 Occurrence of resistance and resistance management

Not expected to be relevant for the product Fly Attract since it is based on olfaction.

2.2.5.7 Known limitations

There are no known limitations to the product Fly Attract.

2.2.5.8 Evaluation of the label claims

The label of the product Fly Attract claims an attractant effect for flies for a period of at least 11 days when used outdoor at a dose of 40 g into 600 mL of water.
The efficacy study has demonstrated that the biocidal product Fly Attract in combination with a trap is effective to attract flies during at least 11 days after the application of the product.

Furthermore, the 2 years old Fly Attract product has shown a similar level of efficacy compared to the fresh product, therefore the product can be considered stable up to 2 years of storage.

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

Not applicable, as the product Fly Attract is not intended to be used with other biocidal products. However, the product Fly Attract should be used in combination with an appropriate trap to catch the insects that it attracts. The trap to be used is not specific to the product and is therefore not included in the product authorization.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The product Fly attract 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.

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 Fly attract 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

No data required since the product contains no substances of concern and its active substance is registered under the Annex I of the BPR.

Other

No other information is required.

Assessment for endocrine disrupting properties for non-active substances

None of the co-formulants shows an alert for endocrine disruptors.

2.2.6.2 Exposure assessment

The product Fly attract 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.

2.2.6.3 Risk characterisation for human health

The product "Fly attract" is not classified and does not contain any classified ingredient or substance of concern. A risk characterisation is not required and authorization is acceptable under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.7 Risk assessment for animal health

The product "Fly attract" is not classified and does not contain any classified ingredient or substance of concern. A risk assessment for animal health is not required and authorization is acceptable under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.8 Risk assessment for the environment

The product Fly attract is not classified and does not contain any classified ingredient or substance of concern. A risk assessment for the environment is not required and

authorization is acceptable under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.

2.2.9 Measures to protect man, animals and the environment

The product Fly attract 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 and authorization is acceptable under the Simplified Authorisation procedure according to Regulation (EU) 528/2012.
Supplemental information: Refer to Summary product caracteristics

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

Not applicable, the biocidal product Fly attract is not intended to be used in combination with other biocidal products.

2.2.11 Comparative assessment

Not applicable.

3 ANNEXES[7]

3.1 List of studies for the biocidal product (family)

Section No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published	Data protection (Yes/No)	Owner
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

3.2 Output tables from exposure assessment tools

Not relevant; no exposure assessments are required.

3.3 New information on the active substance

No new information on the active substances has been provided in support of this biocidal product. *Saccharomyces cerevisiae*, Powdered egg and D-Fructose are listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin.

3.4 Residue behaviour

Not relevant.
The intended uses of Fly attract are not expected to lead to contamination of food/feedstuff.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[8]

Please see section 3.1 above and the efficacy section 2.2.5 of this PAR which summarises these data. All studies have been included and summarised in IUCLID dossier.

3.6 Confidential annex

For confidential data we refer to the separate confidential annex.

3.7 Other

No other information.

7 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

8 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.