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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATION

(submitted by the competent authority)

FRUIT FLY TRAP

Product type 19

Vinegar, concentrated apple juice and D-fructose as included in the Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-SD084765-26

Competent Authority: FR CA

Date: November 2023

Table of Contents

Changes history table

Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
SA-APP	FR CA	BC-SD084765-26	22.11.2023	Initial authorisation	

1 Conclusion

FRUIT FLY TRAP is a ready to use biocidal product containing vinegar, concentrated apple juice and D-fructose as active substances. The product is used as a bait (PT19) by professionel and general public for the control of fruit fly *(Drosophila melanogaster*) in indoor and outdoor areas.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the use fruit fly attractant used by professional and non-professional in indoor and outdoor areas as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

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

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

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

1. The active substances vinegar, concentrated apple juice and D-fructose are listed in Annex I of Regulation (EU) 528/2012 with no restrictions applied
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008[1] is necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.The biocidal product does not contain any non-active substances (so called "co-formulants") which are considered as substances of concern.

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, there are indications that some non-active substances may have endocrine-disrupting properties and these will have to be further investigated.

More information is available in section 2.7 of the PAR and in the confidential annex.

Composition

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

The chemical identity, quantity, requirements for the active substance(s) in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The

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

manufacturer(s) of the active substance(s) are listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

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

Physical, chemical and technical properties

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

Physical hazards and respective characteristics

The product is classified H290 – May be corrosive to metals. No other physical hazards were identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substances, residues, relevant impurities and substances of concern are available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

Efficacy against target organisms

The efficacy of the biocidal product FRUIT FLY TRAP, as ready to use (8 mL trap) or 15 mL or more in combination with an appropriate fruit fly trap , has been shown against fruit flies (*Drosophila melanogaster.*) until 4 weeks after opening when placed at a distance of 1 m to the infestation source and is still effective after 2 years of storage.

Risk assessment for human health

No substances of concern were identified for Human health.

The handling of the product and its intended use do not require personal protective equipment.

Dietary risk assessment

Not relevant. As D-fructose, vinegar and concentrated apple juice are listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin, a dietary risk assessment is not relevant

Risk assessment for the environment

No substances of concern were identified for the environment. The product FRUIT FLY TRAP is not classified for the environment.

2 Information on the biocidal product

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

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

Product type(s)	PT19
Type(s) of formulation	RB – Ready to use

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (eCA/ refMS)	Comment (eCA/refMS)
1	Fruit fly trap	PT19	Fruit flies (*Drosophila melanogaster*)	Bait application	Ready to use (8 mL trap) (indoor) 15 mL or more in combination with an appropriate fruit fly trap (indoor and outdoor)	Non-professional and professional	A	-

Codes for indicating the acceptability for each use

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

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

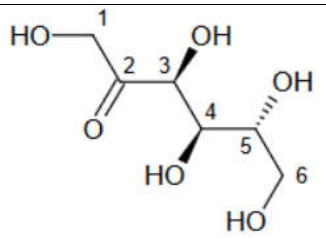
2.3 Identity and composition

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

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

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	D-Fructose
Chemical name	1,3,4,5,6-Pentahydroxy-hexan-2-one
EC number	200-333-3
CAS number	57-48-7
Index number in Annex VI of CLP	Not available
Minimum purity / content	99.5%
Structural formula	

Main constituent(s)	
Common name	Vinegar
Chemical name	Not applicable
EC number	Not applicable
CAS number	8028-52-2
Index number in Annex VI of CLP	Not applicable
Minimum purity / content	Not applicable
Structural formula	Not applicable

Main constituent(s)	
Common name	Concentrated apple juice
Chemical name	Not applicable
EC number	Not applicable
CAS number	Not applicable
Index number in Annex VI of CLP	Not applicable
Minimum purity / content	Not applicable
Structural formula	Not applicable

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

The information on the source(s) of the active substance(s) is not applicable.

2.6 Candidate(s) for substitution

The active substances are included in Annex I (cat. 4 – Traditionally used substances of natural origin) of the BPR and thus are not considered as candidates for substitution.

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

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, there are indications that some of the non-active substances may have endocrine-disrupting properties and these will have to be further investigated. However, at this stage, it is not possible to conclude before the expiration of the legal deadline in the BPR (Articles 30(2), 34(4) and 44(1)) whether the non-active substance(s) should be considered to have endocrine-disrupting properties. More detailed information is available in the confidential annex of the PAR.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Corrosive to metals, Category 1	Corrosive to metals, Category 1
Hazard Pictograms	[GHS05]	[GHS05]
Signal word(s)	Warning	Warning
Hazard statements	H290 – May be corrosive to metal	H290 – May be corrosive to metals
Precautionary statements*	P234 – Keep only in original packaging P390 - Absorb spillage to prevent material damage.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements	-	
Notes	-	

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

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

2.9 Letter of access

A letter of access to the active susbtace data is not applicable for substances included in Annex I of the BPR.

2.10 Data submitted in relation to product authorisation

[Indicate here whether any new data on the active substance(s) and substance(s) of concern have been submitted.

Please note that for (the) active substance(s), only data for endpoints which were not contained in the original approved data set shall be added, i.e. ADS according to Annex II of the BPR.

Example: Due to a new use, additional active substance data according to the information requirements are mandatory.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging[1]	Size/volume of the packaging[2]	Material of the packaging[3]	Type and material of closure(s)	Intended user[4]	Compatibility of the product with the proposed packaging materials (Yes/No)
Single-use Trap	8mL	PET	Layer, PET	Professional Non-professional	Yes Bridging report, see IUCLID section 6.7
Bottle	30mL	PET	screw cap, PP + funnel	Professional Non-professional	Yes
Bottle	30mL 50mL 100mL 250mL 500mL 1L	PET	screw cap, PP	Professional Non-professional	Yes
Bottle	30mL 50mL 100mL 125mL 200mL 250mL 500mL 1L	HDPE	screw cap, HDPE	Professional Non-professional	Yes
Bottle	1L	HDPE	screw cap, HPPP	Professional Non-professional	Yes
Bottle	1L	Coex (HDPE/PA)	screw cap, HDPE	Professional Non-professional	Yes
Can	1L	HDPE	screw cap, HDPE	Professional Non-professional	Yes
Can	2,5L 5L	HDPE	screw cap, HDPE	Professional	Yes

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

3.2 Physical, chemical, and technical properties

Determination of physical, chemical and technical properties is not strictly required for simplified procedures according to Article 25 as detailed in Article 20(1)(b) of the BPR. However, because the Commission was of the opinion that the stability of the product directly affects the efficacy of the product, data on storage conditions, stability and shelf life should be provided (see doc. CA-May14-Doc.5.5 – Final). According to the minutes of the CG-30 meeting (July 2018), for simplified procedures, the shelf life of the product can be set by efficacy studies. For bait-based products this could be the best approach as mentioned in document CA-May14-Doc.5.5 – Final. (footnote of point 3, 7(b)).

Indeed, Fruit Fly Trap is a bait-based product containing some complex food grade active ingredients. In order to be able to analyse the active ingredients, a marker must be selected. This marker, however, does not (only) guarantee the attractiveness and efficacy of the active substances as other constituents in the actives can also contribute to the overall efficacy. Therefore, determining the stability of Fruit Fly Trap by chemical analysis would not guarantee the efficacy at the end of the claimed shelf life even if the markers would be stable and vice versa (significant degradation of the marker would not necessarily mean significant loss of efficacy). The active ingredients are included in Annex I and are therefore considered as low-risk not giving rise to concern (both the actives as potential degradation products).

Because of the above reasons, the stability of Fruit Fly Trap was demonstrated with efficacy studies with both fresh, accelerated stored and 2 year aged product at ambient storage conditions in the commercial packaging. For details on the efficacy, please refer to Section 3.5.

Nevertheless, for the sake of identification of the product, some physical, chemical and technical properties have been determined and are summarized in the table below.

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa				
3.1.1.	Physical state at 20 °C and 101.3 kPa	Organoleptic	Wasptrap (25% d-fructose, 20% vinegar, 10% concentrated apple juice)	Liquid	F-LAB-WASP-1, van der Werff B., 2021
3.1.2.	Colour at 20 °C and 101.3 kPa	Organoleptic	Wasptrap (25% d-fructose, 20% vinegar, 10% concentrated apple juice)	Red/purple	F-LAB-WASP-1, van der Werff B., 2021
3.1.3.	Odour at 20 °C and 101.3 kPa	Organoleptic	Wasptrap (25% d-fructose, 20% vinegar, 10% concentrated apple juice)	Cassis/blackcurrant	F-LAB-WASP-1, van der Werff B., 2021
3.2.	Acidity, alkalinity and pH value	CIPAC MT 191 [using Metrohm Titrino 702 SM, Metrohm pH combi electrode]	Wasptrap (25% d-fructose, 20% vinegar, 10% concentrated apple juice)	3.622±0.002 [undiluted, 20°C, n=3]	F-LAB-WASP-1, van der Werff B., 2021
3.3.	Relative density / bulk density	OECD 109 [using DMA501 Anton Paar]	Wasptrap (25% d-fructose, 20% vinegar, 10% concentrated apple juice)	Density: 1.1427 g/ml ±0.0003 [undiluted, 20°C, n=3]	F-LAB-WASP-1, van der Werff B., 2021
3.4.1.1.	Storage stability test – **accelerated storage**	Waived	-	In accordance with the conclusions of the CG, the shelf-life of the product will be set based on the available efficacy data on aged product. (Cf. PAR section	Minutes CG-30 meeting, related to storage stability in simplified authorisation requests.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				2.2.5) In accordance with the temperature of the accelerated storage stability test used for the efficacy data, do not store at temperatures above 45°C must be stated on label.	
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	Waived	-	In accordance with the conclusions of the CG, the shelf-life of the product will be set based on the available efficacy data on aged product. (Cf. PAR section 2.2.5)	Minutes CG-30 meeting, related to storage stability in simplified authorisation requests.
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Waived	-	The product must not be stored ≤ 0°C. Protect from frost must be stated on label.	-
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Waived	-	Not determined as the product is either packed in opaque packagings or a carton box, thus limiting exposure to light. The label shall also state that the product should be stored in the dark and away from direct sunlight.	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	(Refer to the sections on the storage stability tests)	(Refer to the sections on the storage stability tests)	(Refer to the sections on the storage stability tests) The label shall also state that the product should be kept in its tightly closed original container.	(Refer to the sections on the storage stability tests)
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	(Refer to the sections on the storage stability tests)	(Refer to the sections on the storage stability tests)	(Refer to the sections on the storage stability tests) The label shall also state that the product should be kept in its tightly closed original container.	(Refer to the sections on the storage stability tests)
3.5.1.	Wettability	Waived	-	Not applicable since biocidal product is not a solid preparation to be dispersed in water.	-
3.5.2.	Suspensibility, spontaneity, and dispersion stability	Waived	-	Not applicable since biocidal product does not need to be diluted.	-
3.5.3.	Wet sieve analysis and dry sieve test	Waived	-	Not applicable since biocidal product is a ready to use liquid.	-
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	Waived	-	Not applicable since biocidal product does not need to be emulsified.	-
3.5.5.	Disintegration time	Waived	-	Not applicable since biocidal product is not a tablet and is not used in a water soluble bag.	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	Waived	-	Not applicable since biocidal product is not a granule or tablet. Nor is it intended to be applied in a manner that generates exposure to aerosols, particles or droplets.	-
3.5.7.	Persistent foaming	Waived	-	Not applicable since biocidal product is a ready for use product.	-
3.5.8.	Flowability/pourability/dustability	Waived	-	Not applicable since biocidal product is not granular/a suspension.	-
3.5.9.	Burning rate — smoke generators	Waived	-	Not applicable since the biocidal product is no smoke generator.	-
3.5.10.	Burning completeness — smoke generators	Waived	-	Not applicable since the biocidal product is no smoke generator.	-
3.5.11.	Composition of smoke — smoke generators	Waived	-	Not applicable since the biocidal product is no smoke generator.	-
3.5.12.	Spraying pattern — aerosols / spray	Waived	-	Not applicable since the biocidal product is not an aerosol.	-
3.6.1.	Physical compatibility	Waived	-	The biocidal product is not intended to be added or mixed with any other products.	-
3.6.2.	Chemical compatibility	Waived	-	The biocidal product is not intended to be added or mixed with any other products.	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.7.	Degree of dissolution and dilution stability *(indicate the concentration tested)*	Waived	-	The biocidal product is not intended to be diluted or desolved.	-
3.8.	Surface tension *[indicate the conditions of the test and the concentration tested]*	Waived	-	-	Art.20(1)(b) of EU 528/2012
3.9.	Viscosity *[indicate the shear rate and the temperature tested]*	OECD 114 [using Brookfield DV2T]	Wasptrap (25% d-fructose, 20% vinegar, 10% concentrated apple juice)	At 60 rpm: 3.45 mPa.s ±0.04 At 90 rpm: 3.49 mPa.s ±0.02 At 120 rpm: 3.53 mPa.s ±0.02 At 150 rpm: 3.57 mPa.s ±0.01 [undiluted, 22.6°C] Data at 40°C waived.	F-LAB-WASP-1, van der Werff B., 2021 Art.20(1)(b) of EU 528/2012

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Fruit Fly Trap is a ready for use bait. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Its shelf life is not based on the chemical stability of the product. **Implications for labelling:** -Do not store at temperatures above 45°C -Protect from frost -The product should be stored in the dark and away from direct sunlight. -The product should be kept in its tightly closed original container.

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	UN Manual of Tests and Criteria, subsection 20.3.3.3	Fruit Fly Trap, Batch 30062023 (25% d-fructose, 20% vinegar, 10% concentrated apple juice).	According to the Differential Scanning Calorimetry (DSC) test, no exothermic decompositions were observed with an energy which is equal or exceeding 500 J/g and therefore no onset temperature could be calculated. An endothermic phase change took place between 80°C and 150°C resulting in an endothermic drop Thus, the product Fruit Fly Trap is not considered as explosive.
4.2.	Flammable gases	Waived	-	Not applicable since biocidal product is a liquid.
4.3.	Flammable aerosols	Waived	-	Not applicable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				since biocidal product is a liquid.
4.4.	Oxidising gases	Waived	-	Not applicable since biocidal product is a liquid.
4.5.	Gases under pressure	Waived	-	Not applicable since biocidal product is a liquid.
4.6.	Flammable liquids	Waived	-	Considering the fact that the active substances are included in Annex I of the BPR – category 4, and as such don't give rise to concern for high flammability; Considering the composition of the product where there are no components classified as flammable present; The product is considered not classified.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.7.	Flammable solids	Waived	-	Not applicable since biocidal product is a liquid.
4.8.	Self-reactive substances and mixtures	UN Manual of Tests and Criteria subsection 20.3.3.3	Fruit Fly Trap, Batch 30062023 (25% d-fructose, 20% vinegar, 10% concentrated apple juice)	According to the Differential Scanning Calorimetry (DSC) test, no exothermic decompositions were observed with an evergy which is equal or exceeding 300 J/g and therefore no onset temperature could be calculated An endothermic phase change took place between 80°C and 150°C resulting in an endothermic drop. Thus, the product Fruit Fly Trap is not condisered to be self-reacting.
4.9.	Pyrophoric liquids	Waived	-	Experience in manufacture or

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures. As such, the classification procedure for pyrophoric liquids need not be applied.
4.10.	Pyrophoric solids	Waived	-	Not applicable since biocidal product is a liquid.
4.11.	Self-heating substances and mixtures	Waived	-	The biocidal product is a water based, liquid, Ready to Use product.
4.12.	Substances and mixtures which in contact with water emit flammable gases	Waived	-	The biocidal product is a water based, liquid, Ready to Use product and forms a stable mixture.
4.13.	Oxidising liquids	Justification/theoretical assessment	-	None of the components of the product is classified as oxidising, therefore the product is not classified for

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				oxidising properties.
4.14.	Oxidising solids	Waived	-	Not applicable since biocidal product is a liquid.
4.15.	Organic peroxides	Waived	-	Considering the fact that the active substances are included in Annex I of the BPR – category 4, and as such don't give rise to concern for organic peroxide, this property is considered not applicable.
4.16.	Corrosive to metals	UN Guideline, Test Method C1, Section 37.4 (2016, 6th revision)	Wasptrap (25% d-fructose, 20% vinegar, 10% concentrated apple juice)	The maximum weight loss was 0.86% for the aluminium plates and 5.91% for the steel plates after 28 days exposure time to the test item in a temperature range of 55.0 to 59.5°C. However, any weight loss did not exceed the

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				limit of 51.5% set in table 37.4.4.1 of UN C.1. The maximum intrusion depth was observed to be 89 µm for the aluminium plate that was partly immersed. The maximum intrusion depth was observed to be 684 µm for the steel plate that was not immersed. The maximum intrusion depth exceeds the limit 0f 480 µm set in table 37.4.4.2 of UN C.1. Thus, the test for localized corrosion is considered positive.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	EEC A.15	Fruit Fly Trap, batch N° 30062023 (25% d-fructose, 20% vinegar, 10% concentrated apple juice	No auto-ignition of the test sample was observed below 400°C.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.17.2.	Relative self-ignition temperature for solids	Waived	-	Not applicable since biocidal product is a liquid.
4.17.3.	Dust explosion hazard	Waived	-	Not applicable since biocidal product is a liquid.

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is classified as corrosive to metals, category 1 (H290 - May be corrosive to metals). Other physical hazards are not identified.

3.4 Methods for detection and identification

The product Fruit Fly Trap consists of the active substances D-fructose (25%), concentrated apple juice (10%) and vinegar (20%). These active substances cannot be determined as is.

The vinegar contains 5% acetic acid. Therefore the choice has been made to determine the acetic acid content in the final product as a marker for the vinegar content in final product Fruit Fly Trap. The acetic acid content in the final product is 1%. The acetic acid has been determined using a HPLC-RI method and has been fully validated according to the criteria laid out in SANCO/3030/90 rev.5 (22/03/2019).

The other two active substances (D-fructose and concentrated apple juice) are both sources of sugar. Since the sugar composition of concentrated apple juice differs over the seasons (UVCB substance) and the fact that concentrated apple juice also is a source of D-fructose, the choice has been made to measure the total sugar content in the final product as marker for the combined D-fructose and concentrated apple juice content. The concentrated apple juice has an average Brix value of 70 (referring to a sugar content of 70%). As such, the final product contains 7% sugar coming from the active substance concentrated apple juice. Total sugar content has been measured using a titration method according to Luff-Schoorl in line with NEN 3571 and Regulation (EC) 152/2009 – laying down the methods of sampling and analysis for the official control of feed, Chapter J: Determination of sugar.

The Luff-Schoorl method has been validated according to the criteria laid out in SANCO/3030/90 rev.5 (22/03/2019). However, because Luff-Schoorl is a titration method, only the precision criterium of the method has been conducted as validation of the

method. The criteria specificity, linearity and accuracy have not been checked as these are not applicable for titrations.
Since Fruit Fly Trap does not contain other sources of sugar, interference with other sugar sources is not expected.

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

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method*:* *Acetic acid: 500 mg of sample is taken and dissolved in a 50ml volumetric flask and filled to the mark with water. Analysis is done by HPLC-RI with an Agilent Hiplex H column and isocratic 0.005M H2SO4 elution.* *Total sugar content: according to regulation (EC) 152/2009 p.42-45 J. Determination of sugar. Sugars are extracted in dilute ethanol; the solution is clarified with Carrez solutions I and II. After eliminating the ethanol, the quantities before and after inversion are determined by the Luff-Schoorl method (titration).*											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Acetic acid (marker for active substance vinegar)	0,052 – 0,156 mg/ml Correlation coefficient (r) = 0,99957	No significant interfering peaks. Active ingredient positively identified against reference standard. Retention Time: 18,79 min.	75% 100% 125%	n=2 n=2 n=2	75-125%	103,1%	2,81 %	0.988	6 (1 outlier detected; result based on 5 replicates)	N.A.	RL/21/002 Wronska, 2021
Total sugar content (marker for active	N.A.	N.A.	N.A	N.A.	N.A.	N.A.	N.A.	32.8%	6	N.A.	F-LAB-WASP-2, van der Werff B.,

substances d-fructose and concentrated apple juice)											2021

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.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method, RL21002-1, for the determination of acetic acid (marker component of the active susbtance vinegar) in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. An analytical method, the Luff-Schoorl method, for the determination of the total sugar content as mutual marker for the active substances d-fructose and concentrated apple juice is available. Specificity, linearity, accuracy are not applicable. Precision was checked and found acceptable. There are no substances of concern. Methods for the detection of D-fructose, vinegar and concentrated apple juice in soil, air, water, and animal and human body fluids and tissues are not required.

3.5 Assessment of efficacy against target organisms

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

The product Fruit Fly Trap is intended to be used as a liquid attractant used in combination with a trap (ready to use single use-trap or filling of a re-usable trap), to attract and catch fruit flies (*Drosophila melanogaster* .) in indoor and outdoor areas.

The product is used to protect human health and food.

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

The olfactive attraction of the product is based on food based active substances which lure fruit flies to a trap. Once inside the trap, the insects cannot locate the way out and eventually drown into the liquid.

Effect lasts up to 4 weeks.

3.5.3 Efficacy data

Table 3.8 Efficacy data

<table>
<tr><th>PT and use number</th><th>Test product</th><th>Function / Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects
[address here results related to efficacy of the test product and validity of the test]</th><th>Reference</th><th>Number in IUCLID section 6.7/Test report title</th></tr>
<tr><td>PT19
Attractant</td><td>Fruit Fly Trap (R_600004-vs2-2e)
D-fructose 25% w/w;
Vinegar 20% w/w;
Concentrated apple juice 10% w/w</td><td>Attractant: Fruit flies (Drosophila melanogaster)</td><td>Simulated-use test
Dose = 15 mL
The rooms (30 m³) are set-up with two stools with a height of 50 cm in the centre of the room. On one stool the Fruit fly trap is positioned. On the second stool the alternative food (Alcaine-Colet[3]) is positioned. Trap is placed in 1 m distance to the alternative food. Position of traps varies between left and right to alternative food,</td><td>Mean number of fruit flies caught:
<table>
<tr><td></td><td colspan="3">Number of captures</td></tr>
<tr><td></td><td>T=24hr</td><td>T=48hr</td><td>T=72hr</td></tr>
<tr><td>Placebo</td><td>2</td><td>2</td><td>2</td></tr>
<tr><td>Fresh Batch 22.016</td><td>173</td><td>178</td><td>181</td></tr>
<tr><td>% trapping vs control</td><td>98.8%</td><td>98.9%</td><td>98.9%</td></tr>
<tr><td>Placebo</td><td>1</td><td>1</td><td>1</td></tr>
<tr><td>2 weeks activated Batch 22.016</td><td>153</td><td>172</td><td>175</td></tr>
<tr><td>% trapping vs control</td><td>99.3%</td><td>99.4%</td><td>99.4%</td></tr>
<tr><td>Placebo</td><td>1</td><td>1</td><td>2</td></tr>
<tr><td>4 weeks activated Batch 22.016</td><td>179</td><td>182</td><td>182</td></tr>
<tr><td>% trapping vs control</td><td>99.4%</td><td>99.5%</td><td>98.9%</td></tr>
<tr><td>4 weeks activated Batch 22.032</td><td>160</td><td>175</td><td>182</td></tr>
</table></td><td>Tomakidi, M. 2023
study N° BIO2022-009
Report n°BIO126b-22
R.I=1</td><td>6.7_1</td></tr>
</table>

[3] the alternative feed (Alcaine-colet) is a standardized competition food source highly attractive for fruit flies considered as a strong competitor for other attractants of food sources. The odour of Alcaine-Colet comes close to the odour released by rotting fruit or trash cans even if it is obviously not possible to represent every kind of trash. FR CA can agree with this argumentation.

			depending on replicate (5 replicates). For control, a placebo trap filled with water only was tested directly after activation (fresh), as well as after 2 and 4 weeks after activation at room temperature 200 free-flying Fruit flies, *Drosophila melanogaster* are released into each test room, one hour before product introduction. Evaluation: 8, 24, 48 and 72 hours after trap introduction the number of caught flies in liquid of each trap is evaluated. Product age: Traps are tested fresh, 2 and 4 weeks after activation,	<table><tr><td>**% trapping vs control**</td><td>**99.4%**</td><td>**99.4 %**</td><td>**98.9%**</td></tr><tr><td>6 weeks 45°C and 4 weeks activated Batch 22.032</td><td>163</td><td>173</td><td>180</td></tr><tr><td>**% trapping vs control**</td><td>**99.4%**</td><td>**99.4%**</td><td>**98.9%**</td></tr></table> Conclusion: The fruit fly trap reached a sufficient efficacy (≥ 80%) compared to the control to attract Fruit flies after 6 weeks 45°C and 4 weeks activated (according to the "Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 4.1 February 2022"		

<table>
<tr><td></td><td></td><td></td><td>depending on product batch. Additionally, traps were aged at customer for shelf-life simulation for 6 weeks at 45°C and tested 4 weeks after activation at room temperature.

For activation 15 ml of the liquid attractant is filled into the trap and is aged for the respective test point (fresh, 2 or 4 weeks) at room temperature.

Temperature 21 - 26 °C, relative humidity 30 - 47 %, with artificial light during hours of work (approx. 12 hours light : 12 hours dark), partly additional day light.</td><td></td><td></td><td></td></tr>
<tr><td>PT19 Attractant</td><td>Fruit Fly Trap (R_600004-vs2-2e)

D-fructose</td><td>Attractant: Fruit flies (Drosophila melanogaster)</td><td>Simulated use test
Indoor in homes (kitchen; 18 m²)</td><td><table><tr><th>Time after opening</th><th>% trapping in comparison</th><th>% trapping from the</th></tr></table></td><td>Serrano, B. 2022

study N°</td><td>section 6.7_2</td></tr>
</table>

	25% w/w; Vinegar 20% w/w; Concentrated apple juice 10% w/w		Dose = 15 mL The infestation of the kitchens was artificially done by releasing 300 +/-10 fruit flies in a fruit bowl 1 day before setting the trap. The test was carried out in real practical use conditions 5 replicates The counts of trapping are done 8, 24, 48 and 72 hours after its placement The traps are tested at three dates after opening: 0, 2 and 4 weeks "temperate" climatic conditions between 22 to 26°C representing the average conditions of a house	<table><tr><th></th><th>with control</th><th>original 300 insects</th></tr><tr><td>0</td><td>98.1 %</td><td>90,8 %</td></tr><tr><td>+2 weeks</td><td>98.7 %</td><td>89,9 %</td></tr><tr><td>+4 weeks</td><td>98.4 %</td><td>81,5 %</td></tr></table> The product FRUIT FLY TRAP, used indoor, has reached a sufficient efficacy (≥ 80% compared to the Control or to the number of flies released) to attract the fruit flies *Drosophila melanogaster* according to Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 4.1 February 2022. The efficacy is lasting until 4 weeks after being placed	2777a/0522 R.I=1	

<table>
<tr>
<td>PT19
Attractant</td>
<td>Fruit Fly Trap (R_600004-vs2-2e)

D-fructose 25% w/w;

Vinegar 20% w/w;

Concentrated apple juice 10% w/w</td>
<td>Attractant: Fruit flies (Drosophila melanogaster)</td>
<td>Simulated use test
Outdoor near trash bins
Dose = 15 mL

The infestation of the bins was artificially done by releasing inside the bin 300 +/-10 fruit flies in a fruit bowl 1 day before setting the trap

The test was carried out in real practical use conditions

5 replicates

The counts of trapping are done 8, 24, 48 and 72 hours after its placement

The traps are tested at three dates after opening and storage outside: 0, 2 and 4 weeks

“temperate” climatic conditions</td>
<td>Mean number of fruit flies caught

<table>
<tr><th>Time after opening</th><th>% trapping in comparison with control</th><th>% trapping from the original 300 insects</th></tr>
<tr><td>0</td><td>94.3 %</td><td>55,7 %</td></tr>
<tr><td>+2 weeks</td><td>92.4 %</td><td>53,3 %</td></tr>
<tr><td>+4 weeks</td><td>88.8 %</td><td>43,5 %</td></tr>
</table>

The product FRUIT FLY TRAP, used outdoor, has has reached a sufficient efficacy (≥ 80%) compared to the Control to attract the fruit fly (Drosophila melanogaster) according to Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 4.1 February 2022.

The efficacy is lasting until 4 weeks after being placed.

From the analysis of the flies traps, no other insects than fruitflies were noticed.</td>
<td>Serrano, B. 2022

study N° 2777b/0522

R.I=1</td>
<td>section 6.7_3</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>between 21 to 27°C representing the average conditions of a house</td><td></td><td></td><td></td></tr>
<tr><td>PT19
Attractant</td><td>Wasp trap D20200710°02

D-fructose 25% w/w;
Vinegar 20% w/w;
Concentrated apple juice 10% w/w

2 years aged product, 4 weeks after activation</td><td>Attractant: Fruit flies (Drosophila melanogaster)</td><td>Simulated-use test
Dose = 15 mL
The rooms (30 m³) are set-up with two stools with a height of 50 cm in the centre of the room. On one stool the Fruit fly trap is positioned. On the second stool the alternative food is positioned. Trap is placed in 1 m distance to the alternative food (Alcaine-Colet). Position of traps varies between left and right to alternative food, depending on replicate (5 replicates).
200 free-flying Fruit flies, Drosophila melanogaster are released into each test room,</td><td>Mean number of fruit flies caught 4 weeks after activation:
<table><tr><td></td><td colspan="3">Number of captures</td></tr><tr><td></td><td>T=24hr</td><td>T=48hr</td><td>T=72hr</td></tr><tr><td>Placebo</td><td>1</td><td>1</td><td>1</td></tr><tr><td>Ambient 2 years 20°C</td><td>132</td><td>151</td><td>167</td></tr><tr><td>% of trapping in comparison with the control</td><td>99%</td><td>99.3%</td><td>99.4%</td></tr></table>The product achieves a sufficient level of efficacy (≥ 80%) compared to the control to attract Fruit flies (Drosophila melanogaster), according to the "Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 4.1 February 2022"</td><td>Tomakidi, M. 2023
study N° BIO2022-009
Report n°BIO129a-22

R.I=1</td><td>section 6.7_4</td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>one hour before product introduction.

Evaluation: 8, 24, 48 and 72 hours after trap introduction the number of caught flies in liquid of each trap is evaluated.

Product age: Aged for 2 years at 20 °C and additional 4 weeks after activation at room temperature.

temperature 21 - 25 °C, relative humidity 30 - 47 %, with artificial light during hours of work (approx. 12 hours light : 12 hours dark), partly additional day light.</td><td></td><td></td><td></td></tr>
<tr><td>PT19 Attractant</td><td>Fruit Fly Trap (R_600004-vs2-2e)

D-fructose 25% w/w;

Vinegar 20% w/w;</td><td>Attractant: Fruit flies (Drosophila melanogaster)</td><td>Simulated-use test
Dose = 8 mL in single-use traps (Bridging study)

The rooms (30 m³) are set-up with two stools</td><td>Mean number of fruit flies caught 4 weeks after opening

<table><tr><td></td><td colspan="3">Mean number of fruit flies caught</td></tr><tr><td></td><td>T=24hr</td><td>T=48hr</td><td>T=72hr</td></tr><tr><td>Placebo</td><td>0</td><td>1</td><td>1</td></tr></table></td><td>Tomakidi, M. 2022

study N° BIO2022-058

Report n°BIO097b-</td><td>section 6.7_5</td></tr>
</table>

	Concentrated apple juice 10% w/w 8 weeks at 40°C aged product, 4 weeks after activation		with a height of 50 cm in the centre of the room. On one stool the Fruit fly trap is positioned. On the second stool the alternative food (Alcaine-Colet) is positioned. Trap is placed in 1 m distance to the alternative food. Position of traps varies between left and right to alternative food, depending on replicate (5 replicates). 200 free-flying Fruit flies, Drosophila melanogaster are released into each test room, one hour before product introduction. Evaluation: 8, 24, 48 and 72 hours after trap introduction the number of caught flies in liquid of each trap is evaluated.	<table><tr><td>+4 weeks</td><td>109</td><td>145</td><td>167</td></tr><tr><td>Efficacy compared to the control</td><td>100</td><td>99.3%</td><td>99.4</td></tr><tr><td>% reduction</td><td>54.5%</td><td>72.5%</td><td>83.5%</td></tr></table> Fruit Fly Trap achieves a sufficient level of efficacy (≥ 80%) in comparison to the control to attract Fruit flies (*Drosophila melanogaster*), according to the "Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 4.1 February 2022"	22 R.I=1	

<table>
<tr><td></td><td></td><td></td><td>Product age: 8 weeks shelf-life storage at 40 °C with additional 4 weeks activated at room temperature (opening of entrance hole)

temperature 23 - 25 °C, relative humidity 37 - 47 %, with artificial light during hours of work (approx. 12 hours light : 12 hours dark), partly additional day light.</td><td></td><td></td><td></td></tr>
<tr><td>PT19 attractant</td><td>Fruit Fly Trap (R_600004-vs2-2e)

D-fructose 25% w/w;

Vinegar 20% w/w;

Concentrated apple juice 10% w/w

Batch CH10062022

2 years aged, 4 weeks after activation</td><td>Attractant: Fruit flies (Drosophila melanogaster)</td><td>Simulated-use test
Dose = 15 mL
The rooms (30 m³) are set-up with two stools with a height of 50 cm in the centre of the room. On one stool the Fruit fly trap is positioned. On the second stool the alternative food (Alcaine-Colet) is positioned. Trap is placed in 1 m distance to the alternative food.</td><td>Mean number of fruit flies caught 4 weeks after opening:

<table><tr><td></td><td colspan="4">Number of fruit flies caught</td></tr><tr><td></td><td>8h</td><td>24h</td><td>48h</td><td>72hr</td></tr><tr><td>Placebo</td><td>0</td><td>1</td><td>1</td><td>2</td></tr><tr><td>Ambient 2 year 20°C</td><td>32</td><td>132</td><td>151</td><td>167</td></tr><tr><td>% Efficacy compared to the control</td><td>100%</td><td>99.2%</td><td>99.3%</td><td>98.8%</td></tr><tr><td>% reduction</td><td>16%%</td><td>66%%</td><td>75.5%</td><td>83.5%</td></tr></table>
The product Fruit Fly Trap sufficiently attracts fruit flies after 2 years of storage at room temperature and 4 weeks after opening</td><td>Pagonidis, 2023

Study N° BIO2022-009</td><td>section 6.7_6</td></tr>
</table>

			Position of traps varies between left and right to alternative food, depending on replicate (5 replicates). 200 free-flying Fruit flies, Drosophila melanogaster are released into each test room, one hour before product introduction. Evaluation: 8, 24, 48 and 72 hours after trap introduction the number of caught flies in liquid of each trap is evaluated. Product age: Aged for 2 years at 20 °C and additional 4 weeks after activation at room temperature. Temperature 21 – 25 °C, relative humidity 30 – 47 %, with artificial light during hours of work (pprox.. 12	Fruit Fly Trap achieves a sufficient level of efficacy (≥ 80%) in comparison to the control against Fruit flies (*Drosophila melanogaster*), according to the "Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 4.1 February 2022"		

<table>
<tr><td></td><td></td><td></td><td>hours light : 12 hours dark), partly additional day light.</td><td></td><td></td><td></td></tr>
<tr><td>PT19 attractant</td><td>Fruit Fly Trap 0.1 % aroma

Fruit Fly Trap 0.02 % aroma

Fruit Fly trap blank (0.1 % aroma)

Placebo trap (water)</td><td>Attractant: Fruit flies (Drosophila melanogaster)</td><td>Simulated-use test
Dose = 15 mL
The rooms (30 m³) are set-up with two stools with a height of 50 cm in the centre of the room. On one stool the Fruit fly trap is positioned. On the second stool the alternative food (Alcaine-Colet) is positioned. Trap is placed in 1 m distance to the alternative food. Position of traps varies between left and right to alternative food, depending on replicate (5 replicates).
200 free-flying Fruit flies, Drosophila melanogaster are released into each test room, one hour before product introduction.</td><td>Mean number of fruit flies caught
<table><tr><th></th><th>8h</th><th>24h</th><th>48h</th><th>72hr</th></tr><tr><td>Fruit fly trap 0.1% aroma</td><td>64</td><td>181</td><td>187</td><td>189</td></tr><tr><td>% Efficacy compared to the control (high level)</td><td>100%</td><td>99.4%</td><td>98.9%</td><td>98.4%</td></tr><tr><td>Fruit fly trap</td><td>53</td><td>168</td><td>177</td><td>182</td></tr><tr><td>% Efficacy compared to the control (low level)</td><td>100%</td><td>99.4%</td><td>98.9%</td><td>98.4%</td></tr><tr><td>Fruit fly trap (blank) 0.1% aroma</td><td>2</td><td>22</td><td>25</td><td>28</td></tr><tr><td>Placebo</td><td>0</td><td>1</td><td>2</td><td>3</td></tr></table>
The test results have shown that there is no difference in catch rates in comparison with the control between the formulation containing the higher aroma concentration and the formulation containing a lower concentration of the fruit fly population (no statistical difference).
The blank formulation containing only the co-formulants including the aroma caught only 14% of the fruit fly</td><td>Pagonidis, 2023

Study n° BIO2023-057</td><td>section 6.7_7</td></tr>
</table>

			Evaluation: 8, 24, 48 and 72 hours after trap introduction the number of caught flies in liquid of each trap is evaluated. Temperature 24 – 26 °C, relative humidity 35 – 54 %, with artificial light during hours of work (pprox.. 12 hours light : 12 hours dark), partly additional day light.	population after 72 hours and is thus far below the required 80% reduction. Thus, based on these results, it can be concluded that the aroma has no significant impact on the efficacy of the product. read across between the two formulations		

3.5.4 Efficacy assessment

The product is intended to be marketed as a ready to use single trap containing 8 mL or as a re-usable trap to be filled with 15 mL or more if needed with regard to the size of the trap. The product is intended to be used indoor and outdoor. Following the request for additional data, the application has confirmed that the product ready to use (8 mL) is restricted to indoor use.

In order to support that the aroma/perfume has no significant impact on the efficacy, a simulated use test with a formulation containing the higher content of aroma (as in the study BIO2022-009), a formulation identical to the product Fruit fly trap, a formulation containing the lower content of aroma and a control with water. From the results, it appeared that, in comparison with the control, no significant difference is noticed. It is also shown that the efficacy is brought by the active susbtances contained in the product. Therefore based on this trial, read –across is acceptable

Simulated use tests have been performed with the product FRUIT FLY TRAP and with a variation of the product FRUIT FLY TRAP where the content of aroma/perfume were slightly different.

- the study N° BIO2022-009 of Tomakidi, M. 2023, performed with the product FRUIT FLY TRAP (15 mL), indoor, against fruit flies (*D. melanogaster*), demonstrated an attractiveness higher than 80% in comparison with the untreated control, in presence of an alternative feed (Alcaine-Colet) and up to 4 weeks after activation.
- the study N°2777a/0522 of Serrano, B 2022, performed with the product FRUIT FLY TRAP (15 mL), in kitchens artificialy contaminated with Fruits flies (*D. melanogaster*), demonstrated an attractiveness higher than 80% in comparison with the untreated control in the presence of an alternative feed (fruit bowl) until 4 weeks. A population reduction higher than 80% was also shown until 4 weeks.
- the study N° 2777b/0522 of Serrano, B 2022, performed with the product FRUIT FLY TRAP (15 mL), outdoor near trash bins artificially contaminated with fruit flies (*D. melanogaster*), demonstrated an attractiveness higher than 80 % in comparison with the untreated control until 4 weeks.
- the study BIO2022-058 of Tomakidi, M. 2022, performed with the ready to use trap containing 8 mL of the product FRUIT FLY TRAP 8 weeks aged, indoor, against fruitflies (*D. melanogaster*) demonstrated an attractiveness higher than 80% with the untreated control in presence of an alternative feed (Alcaine-Colet) and up to 4 weeks after activation.

Regarding the shelf life of the product, a simulated use test (study BIO2022-009, bio 129a-22, Tomakidi, M. 2023) with the product WASP TRAP (same as Fruit fly trap, 2 years aged product). This study demonstrated an attractiveness higher than 80% in comparison with the untreated control in presence of an alternative feed (Alcaine-Colet) and up to 4 weeks after activation.
A second simulated use test (study BIO2022-009, bio 126b-22, Tomakidi, M. 2023) with the product FRUIT FLY TRAP, 2 years aged product. This study demonstrated an attractiveness higher than 80% in comparison with the untreated control in presence of an alternative feed (Alcaine-Colet) and up to 4 weeks after activation.
From these studies, a shelf life of 2 years is validated.

Conclusion on efficacy

The efficacy studies has proven that the product Fruit fly trap, is effective to attract fruit flies (*D. melanogaster*) up to 4 weeks after opening, as ready to use trap (trap of 8 mL) in

indoor, and in trap to be filled with at least 15 mL depending on the trap in indoor and oudoor applications.
No efficacy trial has been submitted in order to support the efficacy of the product in outdoor. Furthermore, the studies demonstrate that the product is still efficient after 2 years of storage.

3.5.6 Occurrence of resistance and resistance management

Up to now, no resistance has been identified in the literature review in any fruit fly species, which is attracted by concentrated apple juice and D-fructose.

3.5.7 Known limitations

There is no known limitations to the product FRUIT FLY TRAP.

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

Not applicable, as the product FRUIT FLY TRAP is not intended to be used with other biocidal products.

3.6 Risk assessment for human health

According to Article 25 and Article 20 (1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

3.6.1 Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoints for the active substances and available information for the non-active substances.

The classification for skin irritation and eye irritation has been determined by using the calculation method laid down in the CLP Regulation 1272/2008/EC, based on the available data on each component.
The biocidal product FRUIT FLY TRAP is not classified for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitisation and acute toxicity.

3.6.1.1 Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not classified as skin corrosive or irritant.
Justification for the value/conclusion	The sum of the concentration of the active substance Acetic acid and one co-formulant classified for skin irritation is below the threshold value of 10% to classify the product Skin Irrit. 2, H315.
Classification of the product according to CLP	No classification is required.

3.6.1.2 Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not classified as Eye irritant.
Justification for the value/conclusion	The sum of the concentration of the active substance Acetic acid and two co-formulants classified for eye irritation is below the threshold value of 10% to classify the product Eye Irrit. 2, H319.
Classification of the product according to CLP	No classification is required.

3.6.1.3 Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	One co-formulant of the product FRUIT FLY TRAP contains ingredients classified for skin sensitization, but their concentration in the product is below the generic concentration limit for classification (1% for category 1 and 1B) and for the mention EUH208 (0.1%).
Classification of the product according to CLP	No classification is required.

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

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

3.6.3 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

3.6.4 Exposure assessment and risk characterisation for human health

Not relevant

3.6.5 Dietary risk assessment

Not relevant.
As D-fructose, vinegar and concentrated apple juice are listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin, a dietary risk assessment is not relevant.

3.7 Risk assessment for animal health

Not relevant.

3.8 Risk assessment for environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

3.8.1 Classification

The classification of the product has been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008 and the product is not classified. Moreover, there is no need for risk mitigation measure to protect the environment.

3.8.1.1 Substance(s) of concern

The product FRUIT FLY TRAP does not contain any environmental substance of concern (SoC) according to the EU guidance on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017).

3.8.1.2 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substance(s), refer to the respective section of the confidential annex.

3.9 Assessment of a combination of biocidal products

[For a biocidal product that is intended to be authorised for the use with other biocidal products, refer to the Guidance on the BPR: Volume III Human Health (Part A) to characterise the risk in case of exposure to several products.]

3.10 Comparative assessment

Not relevant, none of the active substance are candidate for substitution or exclusion.

4 Appendices

Calculations for exposure assessment

Not relevant

List of studies for the biocidal product

[List the studies by Reference No (Annex III requirement)/IUCLID Section Number and within a section alphabetically by author.]

Table 4.1 List of studies for the biocidal product

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/ IUCLID Section No.**	**IUCLID Document name**	**Title. Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
[redacted]	2021 February 2021	3	S3_van der Werff, 2021	Wasptrap Physical Chemical analysis F-LAB-WASP-1	Unpublished	Denka International BV Denka Registrations B.V.	No	Yes
[redacted]	2023 August 2023	4.1 4.8 4.17.1	S4.0_Norris (2023)_CoA DSC, Auto-ifnition temp, oxidising	Certificate of Analysis for Auto-Ignition Temperature and DSC Analysis DNA7348	Unpublished	David Norris Analytical Laboraroties Denka Registrations B.V.	No	Yes

[redacted]	2023 August 2023	4.4	S4.4_Norris (2023)_theoretical certificate of oxidising properties for Fruit Fly Trap	Theoretical certificate of oxidising propertis for Fruit Fly Trap	Unpublished	David Norris Analytical Laboratories Denka Registrations BV.	No	Yes
[redacted]	2022 August 2022	4.16	S4.16_Czornik (2022), Determiniation of the metal corrosive properties for Wasptrap	Determination of the metal corrosive properties for "Wasptrap" Mo7418 (study number)	Unpublished	BioGenius GmbH Denka Registrations B.V.	Yes Localized corrosion: No	Yes
[redacted]	2021 March 2021	5	S5_van der Werff, 2021	Wasptrap – total sugars (Luff-Schoorl) analytical method validation F-LAB-WASP-2	Unpublished	Nutrilab B.V. Denka Registrations B.V.	No	Yes
[redacted]	2021 February 2021	5	S5_Wronska, 2021	Validation of an Analytical Method RL21002-1 for the Determination of Acetic Acid in Wasptrap Formulation RL/21/002 (study number)	Unpublished	Battelle UK Denka Registrations B.V.	No	Yes

[redacted]	2023	3.5.3	Biology 126b-22 Biological Test Report 6.7-01	Efficacy of a Fruit fly trap tested at test points fresh (directly after activation), 2 and 4 weeks after activation and tested after shelf-life storage simulation (6 weeks at 45°C) at test point 4 weeks after activation against Fruit flies, Drosophila	Unpublished	Denka Regisitration BV Liesbeth Berg-Meulenberg Gildeweg 37a 3771 NB, Barneveld, Netherlands	No	Yes
[redacted]	2022	3.5.3	2777a - Fruit fly trap - INDOOR FIELD TRIAL_version2 (1) 6.7-02	FIELD TRIAL OF THE EFFICACY OF A FRUIT FLY TRAP Indoor trial	Unpublished	DENKA Registrations BV (The Netherlands)	No	Yes
[redacted]	2022	3.5.3	2777b - Fruit fly trap - OUTDOOR FIELD TRIAL_version2 (1) 6.7-03	FIELD TRIAL OF THE EFFICACY OF A FRUIT FLY TRAP Outdoor trial	Unpublished	DENKA Registrations BV (The Netherlands)	No	Yes
[redacted]	2023	3.5.3	Biology 129a-22 Biological Test Report Ambient 6.7-04	Efficacy of a Wasp trap aged for 2 years at 20 °C and tested after additional 4 weeks of aging at room temperature against Fruit flies, Drosophila melanogaster in 30 m³ test rooms.	Unpublished	DENKA Registrations BV (The Netherlands)	No	Yes

[redacted]	2022	3.5.3	Biology 097a-22 Biological Bridging Test Report (1) 6.7-05	Efficacy of a Fruit fly trap tested after 8 weeks shelf life at 40 °C and 4 weeks ageing opened at room temperature against Drosophila melanogaster in 30 m³ test rooms.	Unpublished	Denka Regisitration BV Liesbeth Berg-Meulenberg Gildeweg 37a 3771 NB, Barneveld, Netherlands	No	Yes
[redacted]	2023	3.5.3	Biology 053-23 - 1 year aged Fruit Fly Trap 6.7-06	Efficacy of a Fruit fly trap (product code: R 600004-vs2- 2e), aged for 1 year at 20°C, tested after additional 4 weeks of aging at room temperature against Fruit flies, Drosophila melanogaster in 30 m³ test rooms.	Unpublished	Denka Registrations B.V.	No	Yes
[redacted]	2023	3.5.3	Biology 057-23 - comparisson different aroma concentrations 6.7-07	Efficacy of a Fruit Fly traps (Batch:30062023), against Fruit flies, Drosophila melanogaster in 30 m³ test rooms.	Unpublished	Denka Registrations B.V.	No	Yes
[redacted]	2023	3.5.3	Biology 126b-22 Biological Test Report 6.7-01	Efficacy of a Fruit fly trap tested at test points fresh (directly after activation), 2 and 4 weeks after activation and tested after shelf-life storage simulation (6	Unpublished	Denka Regisitration BV Liesbeth Berg-Meulenberg Gildeweg 37a 3771 NB, Barneveld, Netherlands	No	Yes

				weeks at 45°C) at test point 4 weeks after activation against Fruit flies, Drosophila				
[redacted]	2022	3.5.3	2777a - Fruit fly trap - INDOOR FIELD TRIAL_version2 (1) 6.7-02	FIELD TRIAL OF THE EFFICACY OF A FRUIT FLY TRAP Indoor trial	Unpublished	DENKA Registrations BV (The Netherlands)	No	Yes
[redacted]	2022	3.5.3	2777b - Fruit fly trap - OUTDOOR FIELD TRIAL_version2 (1) 6.7-03	FIELD TRIAL OF THE EFFICACY OF A FRUIT FLY TRAP Outdoor trial	Unpublished	DENKA Registrations BV (The Netherlands)	No	Yes
[redacted]	2023	3.5.3	Biology 129a-22 Biological Test Report Ambient 6.7-04	Efficacy of a Wasp trap aged for 2 years at 20 °C and tested after additional 4 weeks of aging at room temperature against Fruit flies, Drosophila melanogaster in 30 m³ test rooms.	Unpublished	DENKA Registrations BV (The Netherlands)	No	Yes
[redacted]	2022	3.5.3	Biology 097a-22 Biological Bridging Test Report (1) 6.7-05	Efficacy of a Fruit fly trap tested after 8 weeks shelf life at 40 °C and 4 weeks ageing opened at room temperature against Drosophila melanogaster in 30 m³ test rooms.	Unpublished	Denka Regisitration BV Liesbeth Berg-Meulenberg Gildeweg 37a 3771 NB, Barneveld, Netherlands	No	Yes

[redacted]	2023	3.5.3	Biology 053-23 - 1 year aged Fruit Fly Trap 6.7-06	Efficacy of a Fruit fly trap (product code: R 600004-vs2- 2e), aged for 1 year at 20°C, tested after additional 4 weeks of aging at room temperature against Fruit flies, Drosophila melanogaster in 30 m³ test rooms.	Unpublished	Denka Registrations B.V.	No	Yes
[redacted]	2023	3.5.3	Biology 057-23 - comparisson different aroma concentrations 6.7-07	Efficacy of a Fruit Fly traps (Batch:30062023), against Fruit flies, Drosophila melanogaster in 30 m³ test rooms.	Unpublished	Denka Registrations B.V.	No	Yes

4.1 References

4.1.1 References other than list of studies for the biocidal product

- Last name(s), Initial(s) of the first name(s), Last name(s), Initial(s) of the first name(s). [Title of the publication], *name of the journal*, **number**, year

- Last name(s), Initial(s) of the first name(s), Last name(s), Initial(s) of the first name(s). [Title of the publication], *name of the journal*, **number**, year

4.1.2 Guidance documents

- [Title of the guidance document], year

- [Title of the guidance document], year

4.1.3 Legal texts

- Regulation (EU) No XXX/year of the European Parliament and of the Council of day Month year concerning (topic)

4.1.4 Confidential information

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