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)



SILENCE PIEGE A MOUCHES DE FRUIT

Product type 19

Concentrated apple juice as included in the Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-VP071283-16

Competent Authority: FR CA

Date: [day Month year]

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**Changes history table**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| SA-APP | *FR* | BC-VP071283-16 | 26.08.2022 | *Initial assessment* |  |

# Conclusion

SILENCE PIEGES A MOUCHES DE FRUIT is a bait concentrate containing vinegar as active substance. The product is used as a PT19 by non-professionals users for the control of fruit flies.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised to control wasps by non-professional users, 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 substance vinegar is listed in Annex I of Regulation (EU) 528/2012 and satisfies the restriction “ Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food).”.
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 of the product SILENCE PIEGE A MOUCHES DE FRUIT according to Regulation (EC) No 1272/2008[[1]](#footnote-2) is not necessary.

The biocidal product does not contain any non-active substances which are considered as substances of concern.

The biocidal product should be considered not to have endocrine-disrupting properties*.*

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

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

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 of the biocidal product is listed in section 1.4 of the SPC.

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

**Conclusions of the assessments for each area**

The intended use as applied for by the applicant has 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 biocidal product is classified as corrosive to metal H290 cat 1.

More information is available in section 3.3 of the PAR.

Methods for detection and identification

The submission of analytical methods for active substances is not part of the data requirements 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.

Efficacy against target organisms

The efficacy of the biocidal product SILENCE PIEGE A MOUCHE DE FRUIT, as ready to use (full bottle of 15 mL combined to a glue trap), has been shown against fruit flies (*Drosophila melanogaster*) until 8 weeks after opening and is still effective after 3 years of storage.

More information is available in section 3.5 of the PAR.

Risk assessment for human health

No substances of concern regarding human health were identified.

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

Risk assessment for the environment

No substances of concern regarding environment was identified.

**Post-authorisation conditions**

None

# Information on the biocidal product

## 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** | **Trap bait** |

## 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 number1** | **Use description2** | **PT3** | **Target organisms4** | **Application method5** | **Application rate6**  **(min-max)** | **User category7** | **Conclusion**  **(eCA/ refMS)8** | **Comment (eCA/refMS)9** |
| [1] | Fruit fly trap | PT19 | Fruit flies (*Drosophila melanogaster*) | Bait application | Ready to use (15mL full bottle combined to a glue trap) | Non-professional | A |  |

1 Use number (as applied for), as indicated in the SPC

2 Title of the specific use (as applied for), as indicated in the SPC

3 Product type(s) of the use(s)

4 Target organisms, group of organisms

5 Application method for the specific use

6 Min-max. application rate of the product for the specific use

7 User categor(y/ies), e.g. general public, non-professional, professional, industrial

8 eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

*Codes for indicating the acceptability for each use*

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

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

## Identity and 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 of the PAR.

According to the information provided:

* The product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.
* All the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex.

## Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **Common name** | Vinegar (food grade containing a maximum of 10% acetic acid) |
| **Chemical name** | *-* |
| **EC number** | *-* |
| **CAS number** | 8028-52-2 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | Not applicable |
| **Structural formula** | - |

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

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

## Candidate(s) for substitution

Not relevant

## 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, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

## Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

|  | **Classification** | **Labelling** |
| --- | --- | --- |
| **Hazard Class and Category code** | Met. Corr. 1 |  |
| **Hazard Pictograms** |  |  |
| **Signal word(s)** | Warning | Warning |
| **Hazard statements** | H290: 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]](#footnote-3), are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

## Letter of access

*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.*

## Data submitted in relation to product authorisation

*Please refer to section 4.3.*

## Similar conditions of use across the Union

This section is not relevant.

# Assessment of the biocidal product

## Packaging

Table 3.1 Packaging

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 30 mL | PET | HDPE cap | Non professional | Yes |

## Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product/batch (AS% w/w)** | **Results** | **Reference** | **FR-CA comments** |
| --- | --- | --- | --- | --- | --- | --- |
| 3.1. | Appearance at 20 °C and 101.3 kPa | Visual method | FRUIT FLY TRAP  Batch n° SCHO-103 WT  100% w/w vinegar with max 10% acetic acid | Homogenous red liquid | Stephan Schopf, S. (2021)  Report n° 2021/06-001 | Acceptable |
| 3.1.1. | Physical state at 20 °C and 101.3 kPa |
| 3.1.2. | Colour at 20 °C and 101.3 kPa |
| 3.1.3. | Odour at 20 °C and 101.3 kPa | - | FRUIT FLY TRAP  Batch n° SCHO-103 WT  100% w/w vinegar with max 10% acetic acid | Typical vinegar odour | Stephan Schopf, S. (2021)  Report n° 2021/06-001 | Acceptable |
| 3.2. | Acidity, alkalinity and pH value | CIPAC MT 75.3 | FRUIT FLY TRAP  Batch n° SCHO-103 WT  100% w/w vinegar with max 10% acetic acid | pH of neat formulation at 20 ± 1 °C: 2.75 | Stephan Schopf, S. (2021)  Report n° 2021/06-001 | Acceptable |
| 3.3. | Relative density / bulk density | - | - | Waived | - | Acceptable  Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012 |
| 3.4.1.1. | Storage stability test – **accelerated storage** | - | FRUIT FLY TRAP  Batch n° SCHO-103 WT  100% w/w vinegar with max 10% acetic acid | FRUIT FLY TRAP was stored in 30 mL PET bottle during 8 weeks at 20 °C.   |  |  |  | | --- | --- | --- | |  | **Initial** | **After 8 weeks at 20 °C** | | **Appearance** | Homogenous red liquid with typical vinegar odour. | | | **Packaging** | The containers didn’t present any deformation (denting or ballooning) in bottom, top and lateral layers. Container sealed and without leakages. | | | **Packaging weight** | 28.6 | 28.5 | | **Packaging weight variation** |  | - | | **pH** | 2.75 | 2.76 | | **Viscosity** Flow time  (*DIN ISO 53211*) | 2.3 s | 2.3 s |   FRUIT FLY TRAP was stored in 30 mL PET bottle during 8 weeks at 40 °C.   |  |  |  | | --- | --- | --- | |  | **Initial** | **After 8 weeks at 40 °C** | | **Appearance** | Homogenous red liquid with typical vinegar odour. | | | **Packaging** | The containers didn’t present any deformation (denting or ballooning) in bottom, top and lateral layers. Container sealed and without leakages. | | | **Packaging weight** | 28.6 | 28.3 | | **Packaging weight variation** |  | - | | **pH** | 2.75 | 2.79 | | **Viscosity** Flow time  (*DIN ISO 53211*) | 2.3 s | 2.3 s | | Stephan Schopf, S. (2021)  Report n° 2021/06-001 | Acceptable.  The product should be stored at temperature below 40°C. |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | *-* | - | Waived | - | Acceptable  In accordance with the conclusions of the CG (Minutes CG-30 meeting, related to storage stability in simplified authorisation requests), the shelf-life of the product will be set based on the available efficacy data on aged product (Cf. PAR section 3.5). |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** |  | FRUIT FLY TRAP  Batch n° SCHO-103 WT  100% w/w vinegar with max 10% acetic acid | FRUIT FLY TRAP was stored in 30 mL PET bottle during 8 weeks at 0 °C.   |  |  |  | | --- | --- | --- | |  | **Initial** | **After 8 weeks at 0 °C** | | **Appearance** | Homogenous red liquid with typical vinegar odour. | | | **Packaging** | The containers didn’t present any deformation (denting or ballooning) in bottom, top and lateral layers. Container sealed and without leakages. | | | **Packaging weight** | 28.6 | 28.5 | | **Packaging weight variation** |  | - | | **pH** | 2.75 | 2.84 | | **Viscosity** Flow time  (*DIN ISO 53211*) | 2.3 s | 2.3 s | | Stephan Schopf, S. (2021)  Report n° 2021/06-001 | Acceptable  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 | *-* | Acceptable  Effects of light are not examined. The mitigation measure “Store away from light” is stated on the label. |
| 3.4.2.2. | Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See 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** | - | - | See storage stability tests | - | - |
| 3.5.1. | Wettability | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.2. | Suspensibility, spontaneity, and dispersion stability | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.3. | Wet sieve analysis and dry sieve test | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.4. | Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.5. | Disintegration time | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.7. | Persistent foaming | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.8. | Flowability/pourability/dustability | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.9. | Burning rate — smoke generators | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.10. | Burning completeness — smoke generators | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.11. | Composition of smoke — smoke generators | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.5.12. | Spraying pattern — aerosols / spray | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.6.1. | Physical compatibility | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.6.2. | Chemical compatibility | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.7. | Degree of dissolution and dilution stability | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 3.8. | Surface tension | - | - | Waived | - | Acceptable  Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012 |
| 3.9. | Viscosity | DIN EN ISO 53211  (Flow cup method) | FRUIT FLY TRAP  Batch n° SCHO-103 WT  100% w/w vinegar with max 10% acetic acid | Flow time: 2.3 s | Stephan Schopf, S. (2021)  Report n° 2021/06-002 | Acceptable |

Table 3.3 Conclusion on physical, chemical, and technical properties

|  |
| --- |
| **Conclusion on physical, chemical, and technical properties** |
| FRUIT FLY TRAP is a ready to use water based liquid formulation. The product is an homogenous red liquid with typical vinegar odour. At 20°C, its pH is 2.75.  As per CG-30 (2018), it was agreed that - in the case of a simplified authorisation - the shelf-life of a product could be set based on either efficacy data or long term chemical storage stability data at ambient temperature. As no storage stability data are available to supported the claimed shelf-life. Shelf life is by available efficacy trials on aged product and it set to 3 years.  **Implications for labelling:** “Protect from frost”; “Store away from light”; “Store at temperature below 40°C”  **Shelf-life:** 3 years  **Classification related to physical, chemical and technical properties of the product:** None |

## 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** | **Reference** | **FR-CA comments** |
| --- | --- | --- | --- | --- | --- | --- |
| 4.1. | Explosives | - | - | 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 explosiveness, this property is considered not applicable. | - | Acceptable |
| 4.2. | Flammable gases | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 4.3. | Flammable aerosols | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 4.4. | Oxidising gases | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 4.5. | Gases under pressure | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 4.6. | Flammable liquids | - | - | 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 high flammability, this property is considered not applicable. | - | Acceptable |
| 4.7. | Flammable solids | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 4.8. | Self-reactive substances and mixtures | - | - | Waived - None of the components of the product is classified as having self-reactive properties. | - | Acceptable |
| 4.9. | Pyrophoric liquids | - | - | Waived - Experience in manufacture or 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. | - | Acceptable |
| 4.10. | Pyrophoric solids | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 4.11. | Self-heating substances and mixtures | - | - | Waived - Not relevant because the formulation is a ready to use water-based formulation. | - | Acceptable |
| 4.12. | Substances and mixtures which in contact with water emit flammable gases | - | - | Waived - Not relevant because the formulation is a ready to use water-based formulation. | - | Acceptable |
| 4.13. | Oxidising liquids | - | - | 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. | - | Acceptable |
| 4.14. | Oxidising solids | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 4.15. | Organic peroxides | - | - | 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 organic peroxides, this property is considered not applicable. | - | Acceptable |
| 4.16. | Corrosive to metals | Method 37.4 C.1 (UN Handbook) | FRUIT FLY TRAP  (100% Vinegar (food grade containing a maximum of 10% acetic acid))  Batch n° SCHO-102FFT | - Surface Corrosion:   |  |  |  |  | | --- | --- | --- | --- | | Exposure time | Criterion for mass\* loss | Mass loss found for Steel (in %) | Mass loss found for Aluminium (in %) | | 28 days | 51.5 % | 85.4 % | 3.5 % |   \* value calculated based on a 6.25 mm/year corrosion rate  - Leak Corrosion:   |  |  |  |  | | --- | --- | --- | --- | | Exposure time | Criterion for corrosion attack (in μm) | Found for Steel (in μm) | Found for Aluminium (in μm) | | 28 days | 480 μm | 710 μm | 500 μm |   Conclusion:  FRUIT FLY TRAP is therefore classified as “corrosive” to steel (1.0037) following the method 37.4 C.1 of the UN Handbook sixth revised edition, UN, 2015.  FRUIT FLY TRAP is therefore classified as “corrosive” to aluminium (7075-T6) following the method 37.4 C.1 of the UN Handbook sixth revised edition, UN, 2015. | Determination of the corrosion of metals Silence piège à mouches des fruits Fruit Fly Trap  Friedl, I. (2022)  Report n° B220397.002 | Acceptable  FRUIT FLY TRAP is classified as corrosive to metals Cat. 1. |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) | - |  | 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. |  |  |
| 4.17.2. | Relative self-ignition temperature for solids | - | - | Not relevant for a ready to use liquid formulation | - | - |
| 4.17.3. | Dust explosion hazard | - | - | Not relevant for a ready to use liquid formulation | - | - |

Table 3.5 Conclusion on physical hazards and respective characteristics

|  |
| --- |
| **Conclusion on physical hazards and respective characteristics** |
| In line with the criteria for simplified authorisation, according to Article 25 of the BPR, the product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties. It is classified as corrosive to metals Cat. 1 (H290)  **Classification related to physical hazards and respective characteristics of the product:** H290 as mentioned in CLP regulation |

## Methods for detection and identification

The providing of an analytical method for active substances is not part of the data requirements 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.

Moreover, since no measurement of active substances content has been required, e.g. in stability studies, no analytical method needs to be developed and validated.

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 3.12 Conclusion on methods for detection and identification

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| --- |
| **Conclusion on methods for detection and identification** |
| As stability data is performed based on efficacy data, no analytical method is required. |

## Assessment of efficacy against target organisms

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

The product SILENCE PIEGE A MOUCHE DE FRUIT is a combination of liquid attractant contained in a bottle and adhesive trap used against fruit flies (*Drosophila spp.*) for indoor use. The product is used to attract and trap this insect on adhesive trap inner sides facing the bottle.

The product is used to protect human health and food.

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

The product SILENCE PIEGE A MOUCHE DE FRUIT is a combination of adhesive trap with natural attractant contained in a bottle for capturing fruit flies. Due to the specific aroma of the attractant, fruit flies will be captured on the adhesive inner sides facing the bottle. It is an olfactory attractant.

Effect lasts up to 8 weeks.

## 

### Efficacy data

Table 3.13 Efficacy data

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PT and use number** | **Test product** | **Function / Test organism(s)** | **Test method / Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** | **Number in IUCLID section 6.7/Test report title** |
| PT19  Attractant | Silence Fruit Fly Trap (identical to SILENCE PIEGE A MOUCHE DE FRUIT)  Code: SCHO-102FFT, LOT: 22018-FFT  100% vinegar  3 year old formulation + 8 weeks open lid, covered with mesh | Attractant:  Fruit flies (*Drosophila melanogaster*) | Simulated-use test  Dose = 15 mL (entire bottle)  Test conducted in a ventilated room (74,25 m3). Table was located in the room, (the position of the table in each repetition was different). A plastic box containing alternative feed source (a mixture of sliced fruit and vegetable) was placed at the end of the table.  Approximately 250 fruitflies were released centrally in the room and allowed to acclimatize for one hour.  After 1 hour, the product was positioned in the room, onto the opposite end of the table than alternative feed (distance 1.5m).  After 24 hours, the fruits flies in the attractant bottle and on the adhesive surface were counted.  The test was performed in the same manner for untreated control (adhesive trap + bottle filled with water).  5 replicates  Temperature: 25°C +/-2°C, RH= 40-60% | Number of fruits flies captured in trap and non-captured in each test:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Trial N°** | **Trap\* (adhesive + bottle)** | **Alternative feed\*\*** | **Free in the room or dead** | **Total** | | 1 | 200 | 92 | 17 | 309 | | Control 1 | 3 | 148 | 166 | 317 | | 2 | 79 | 57 | 129 | 265 | | Control 2 | 2 | 195 | 86 | 283 | | 3 | 167 | 92 | 36 | 295 | | Control 3 | 3 | 163 | 98 | 263 | | 4 | 92 | 177 | 32 | 301 | | Control 4 | 2 | 257 | 28 | 287 | | 5 | 182 | 124 | 9 | 315 | | Control 5 | 4 | 166 | 115 | 285 |   (\*): for control bottle is filled with 15mL of water  (\*\*): Total of flies on banana, tangerine, kiwi and tomato  Calculation of the relative efficiency R   |  |  |  | | --- | --- | --- | | **Trial N°** | **Mortality (%)** | **Corrected efficacy (%)\*\*\*** | | 1 | 66.2 | 65.86 | | Control 1 | 1 | | 2 | 30.9 | 30.41 | | Control 2 | 57.8 | | 3 | 57.8 | 57.33 | | Control 3 | 1.1 | | 4 | 31.3 | 30.82 | | Control 4 | 0.7 | | 5 | 58.5 | 57.91 | | Control 5 | 1.4 | | **mean** | **-** | **48.28** |   (\*\*\*): Corrected efficacy =  (mortality (%) in trap test – mortality (%) in control/100 - mortality (%) in control) x 100  **Conclusion:**  The fruitfly trap reached corrected efficacy of 48.28% in comparison to the untreated control.The required efficacy of >80% was not reached, therefore the efficacy of the product was not proved in this trial. | M. Kulma, 2021  RI=3 (supportive data)  The minimum required efficacy of >80% was not reached. | Number: 211362 |
| PT19  Attractant | Silence Fruit Fly Trap (identical to SILENCE PIEGE A MOUCHE DE FRUIT)  Code: SCHO-102FFT, LOT: 22018-FFT  100% vinegar  3 year old formulation + 8 weeks open lid, covered with mesh | Attractant:  Fruit flies (*Drosophila melanogaster*) | Simulated-use test  Dose = 15 mL (entire bottle).  Test conducted in a ventilated room (74,25m3). Table was located in the room, (the position of the table in each repetition was different). A plastic box containing alternative feed source (whole fruits, each in a separate container) was placed on the table.  Approximately 250 fruitflies were released centrally in the room and allowed to acclimatize for one hour.  After 1 hour, the product was positioned in the room, on the table next to the alternative feed source (distance 0.5m).  After 24 hours, the fruits flies in the attractant bottle and on the adhesive surface were counted.  The test was performed in the same manner for untreated control (adhesive trap + bottle filled with water).  5 replications  Temperature: 25°C +/-2°C, RH= 40-60% | Number of fruits flies captured in trap and non-captured in each test   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Trial N°** | **Trap\* (adhesive + bottle)** | **Alternative feed\*\*** | **Free in the room or dead** | **Total** | | 1 | 239 | 0 | 14 | 253 | | Control 1 | 3 | 58 | 205 | 266 | | 2 | 237 | 6 | 14 | 257 | | Control 2 | 2 | 69 | 188 | 259 | | 3 | 223 | 14 | 14 | 251 | | Control 3 | 4 | 58 | 209 | 271 | | 4 | 311 | 8 | 13 | 332 | | Control 4 | 3 | 78 | 172 | 253 | | 5 | 232 | 8 | 15 | 255 | | Control 5 | 2 | 87 | 161 | 250 |   (\*): for control bottle is filled with 15mL of water  (\*\*): Total of flies on banana, apple and kiwi  Calculation of the relative efficiency R   |  |  |  | | --- | --- | --- | | **Trial N°** | **Mortality (%)** | **Corrected efficacy (%)\*\*\*** | | 1 | 94.47 | 94.41 | | Control 1 | 1.13 | | 2 | 92.22 | 92.16 | | Control 2 | 0.77 | | 3 | 88.84 | 88.68 | | Control 3 | 1.45 | | 4 | 93.67 | 93.59 | | Control 4 | 1.19 | | 5 | 90.98 | 90.91 | | Control 5 | 0.80 | | **mean** | **-** | **91.55** |   (\*\*\*): Corrected efficacy =  (mortality (%) in trap test – mortality (%) in control/100 - mortality (%) in control) x 100  **Conclusion:**  The fruit fly trap reached corrected efficacy of 91.95% in comparison to the untreated control. The product fulfils the required efficacy of > 80% of attracted flies. | M. Kulma, 2021  RI=1 | Number: 211479 |

### Efficacy assessment

Two simulated-use trials have been performed with the product Silence Fruit Fly Trap identical to SILENCE PIEGE A MOUCHE DE FRUIT (SCHO-102FFT, 100% vinegar) on fruit flies (*Drosophila melanogaster*) with an aged of 3 years old and 8 weeks open lid. The products were tested during 24 hours.

In the study n°211362 of M. Kulma, 2021, the minimum required efficacy of >80% was not reached, the efficacy of the product was not proved in this trial. The applicant justified this result that test n°211362 was performed with sliced fruit and vegetable. Indeed, the intended use is not to protect cut or sliced exposed fruit from the presence and further development of fruit flies, but to protect fresh fruit taken home from the grocery store and presented in an exposed fruit basket just like simulated in test n°211479.

In the study n°211479 of M. Kulma 2021, the product demonstrates an attractiveness of 91.55% in comparison with the untreated control in presence of alternative feed (whole fruits). Therefore, the product fulfils the required efficacy of > 80% of attracted flies and is efficient indoor against *Drosophila melanogaster* up to 8 weeks.

Regarding the shelf-life of the product, no preservative is present in the composition of the product. As a 3 years aged product was tested with a successful efficacy, then based on the TAB v2.2 2020, a shelf-life of 3 years can be validated.

### Conclusion on efficacy

The efficacy studies prove that the product SILENCE PIEGE A MOUCHE DE FRUIT, is effective to attract fruit flies up to 8 weeks after opening, as ready to use (full bottle of 15 mL combined to a glue trap).

Furthermore, the studies demonstrate that the product is still efficient after 3 years of storage.

### Occurrence of resistance and resistance management

Not expected to be relevant for the product SILENCE PIEGE A MOUCHE DE FRUIT since it is based on olfaction.

### Known limitations

There are no known limitations to the product SILENCE PIEGE A MOUCHE DE FRUIT.

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

Not applicable, as the product SILENCE PIEGE A MOUCHE DE FRUIT is not intended to be used with other biocidal products.

## 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.

### 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 substance and available information for the non-active substance.

The classification of the product SILENCE PIEGE A MOUCHE DE FRUIT has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

The biocidal product SILENCE PIEGE A MOUCHE DE FRUIT is not classified for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitization and acute toxicity.

#### Skin corrosion and irritation

Table 3.17 Conclusion used in Risk Assessment – 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 active substance Acetic acid is present in the product at a concentration below the specific concentration limit to classify the product Skin Irrit. 2, H315. |
| Classification of the product according to CLP | No classification is required. |

#### Eye irritation

Table 3.22 Conclusion used in Risk Assessment – Eye irritation

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not classified as Eye irritant. |
| Justification for the value/conclusion | The active substance Acetic acid is present in the product at a concentration below the specific concentration limit to classify the product Eye Irrit. 2, H319. |
| Classification of the product according to CLP | No classification is required. |

### 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)).

### Available toxicological data relating to endocrine disruption

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

### Dietary risk assessment

As Vinegar is 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 animal health

Not relevant

## Risk assessment for the 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.

### Classification

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.

The active substance is listed in Annex I of Regulation (EU) No 528/2012 without any restriction for the environment and there is no need for risk mitigation measure to protect the environment.

### Substance(s) of concern

The product SILENCE PIEGE A MOUCHE DE FRUIT 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).

### Screening for endocrine disruption relating to non-target organisms

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

## Assessment of a combination of biocidal products

The biocidal product SILENCE PIEGE A MOUCHES DE FRUIT is not intended to be used with other biocidal products.

## Comparative assessment

As active substances are listed in Annex I of Regulation (EU) No 528/2012, a comparative assessment is not relevant.

# Appendices

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

No new information on the active substances is available

No new information on the substances of concern is available

## List of studies for the biocidal product

See IUCLID

## Confidential information

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

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 [↑](#footnote-ref-2)
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>. [↑](#footnote-ref-3)